REAUTHORIZATION OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

HEARINGS

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

SECOND SESSION

ON

S. 2245

A BILL TO AMEND AND EXTEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AS AMENDED, FOR TWO YEARS;

S. 2620

A BILL TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT; AND

S. 2621

A BILL TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

JUNE 21 AND 22, 1982

Printed for the use of the
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REAUTHORIZATION OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

MONDAY, JUNE 21, 1982

U.S. Senate,
Committee on Agriculture, Nutrition, and Forestry,
Washington, D.C.

The committee met, pursuant to notice, at 2 p.m., in room 324, Russell Senate Office Building, Hon. Jesse Helms (chairman of the committee) presiding.

Present: Senators Helms and Melcher.

STATEMENT OF HON. JESSE HELMS, A U.S. SENATOR FROM NORTH CAROLINA

The Chairman. The committee will come to order.

We are substantially lacking a quorum but, fortunately, we do not need one for hearings, and all that is said and done here will be a matter of record for committee members to peruse and study.

I want to extend a welcome to all of our participants and all of our guests.

The Chair would mention that this is the first of three public sessions to take testimony on proposed amendments to the Federal Insecticide, Fungicide, and Rodenticide Act, commonly known as FIFRA.

The second and third sessions of this hearing will be held tomorrow, and will be chaired by Senator Hayakawa in the morning and Senator Lugar in the afternoon.

For the record, the Chair would note that FIFRA is the basic Federal statute regulating the use of pesticides in the United States. At the heart of this statute is a complex program for registration, by the EPA, of all pesticides proposed for sale and use in the United States.

The objective of this program is to insure that only safe and effective pesticides make their way into the marketplace. The process of developing a new pesticide and getting it registered is expensive, complicated, and frequently slow. In many cases, the necessary testing takes years, costs millions of dollars, and generates thousands of pages of data. Obviously, these research and development efforts must lead to company profits or companies will not undertake them in the future. Healthy competition among pesticide producers, obviously, is necessary to insure the continued investment of capital into the development of new pesticides that are safe and effective and that are essential to maintaining the high level of agricultural production in this country. The registration process must be designed so that it does not erode this competition between pesticide producing companies and so that these vital products are readily available to farmers.

In this connection, proposed legislation has been introduced by Senator Hayakawa, S. 2621, and myself, S. 2620, to amend FIFRA to correct certain problems that have come up in connection with this program.

Some of the major issues raised in these bills are: The modification of the additional data provision to provide for more equitable sharing by registrants of the cost of producing additional data requested by the EPA Administrator; the extension of a period of exclusive use of registration data from 10 to 15 years and the phasing out of data compensation; the termination of EPA's cite-all policy; the modification of the provisions governing disclosure of registration data by EPA to the public; and the establishment of certain requirements applicable to the administration of pesticide registration programs by the States.

We are all aware that various other issues have also been raised; therefore, the Chair expects to hear testimony regarding those issues as well as on the pending legislation.

So, at this time, the Chair would recognize the first witness, Hon. John Todhunter, Assistant Administrator of EPA.

Mr. Todhunter, you may proceed.

STATEMENT OF HON. JOHN A. TODHUNTER, ASSISTANT ADMINISTRATOR, PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Dr. TODHUNTER. Good afternoon, Mr. Chairman.

I am John Todhunter, the Assistant Administrator for Pesticides and Toxic Substances of the Environmental Protection Agency. I am delighted to be here this afternoon to discuss the Agency's views on S. 2620, a bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act. I will also comment briefly on S. 2621.

As you know, S. 2620 was only recently introduced and involves a number of complex issues that do require review and input from other agencies as well as EPA before the administration can provide you with a definitive position on this bill. However, in light of months of participation in discussions of similar legislation on the House side, the Agency believes that the legislative proposals in S. 2620 are probably workable.

Since most of the discussion on the FIFRA amendments has centered on sections 3, 10, and 24(a) of the act, I would like to devote the rest of my testimony to these issues. I would like to emphasize that we are particularly concerned about section 24(a) amendments, as I will detail later in my testimony.

We have, since the last markups in the House, been trying to find a middle ground with the industry and a regulated community on how to handle exclusive use of data for new uses. This is the issue of most concern to the Agency from a purely administrative standpoint.

From EPA's point of view, we believe that the language in the Senate's bill articulates that middle ground. Instead of a myriad of different exclusive use "time clocks," there will be two timeclocks for new chemicals; that is, a 15-year exclusive use clock which begins on the date of original registration and a second exclusive use clock which begins on the date the first new use is added to the registration. There will also be one 15-year exclusive use period from 1978 to 1993, covering data supporting new uses of old chemicals. This treatment of the exclusive use provisions will, we hope, increase the industry's incentive for developing new uses while at the same time reducing the tracking and administrative requirements to a manageable level for the Agency.

We have no problem with the rest of the section 3 language. I would like to emphasize here, as I have in previous testimony, that changing our procedures and regulations will not be without some cost in our ability to process registration actions.

I feel, I believe, that we are making excellent progress on the goal of this administration to respond to pesticide registration actions in a timely manner. We are steadily improving the turnaround times and reducing the backlogs. I continue to be concerned that the changes to FIFRA not be accomplished at the expense of our streamlining efforts, or other resources to maintain our public health protection responsibilities.

Back in February of this year, Chairman Brown and ranking minority member Wampler of the House Subcommittee on Department Operations, Research, and Foreign Agriculture, urged me to try to find a compromise on the issue of release of health and safety studies in section 10 of FIFRA.

EPA sponsored several meetings to get the public interest groups and the industry together to try to find some workable solution. The objective, of course, is to permit the public to have access to information which underlies our pesticide decisions and, at the same time, to prevent disclosure of expensive health and safety data to industry competitors.

In my view, the changes to section 10, as proposed in S. 2620, strike a fair balance between those competing goals. This is a very difficult area, Mr. Chairman, one in which I have personally spent a lot of time in talking to environmental, labor, and farmworker groups, and to the pesticide producing industry. All do have legitimate interests. I think they are served well by your bill. The language does not restrict the public's access to data. Some restrictions on reproducing and publishing data have been added, but these changes are only designed to prevent data from being inadvertently disclosed to competitors in the marketplace who legally have no right to it.

While the Senate bill, S. 2620, does not propose to amend FIFRA section 24(a), this issue will undoubtedly arise during your deliberations on S. 2621, which does focus on State authorities under the act.

Now, let me say at the outset that the administration has been on record for some months now opposing the proposed changes to States' authorities. We are very sympathetic to the concerns expressed by industry that a product which has met our stringent Federal registration requirements ought not have to undergo a myriad of additional data requirements and clearances. We are, however, troubled by the potential impact of amending section 24(a) on States' prerogatives.

The Agency has also opposed the role of arbitrator it would assume between industry and the States as to what data are appropriate to address local concerns. We do not believe that we are in a position to second guess what information a State government needs or does not need to respond to local conditions. We are glad that S. 2620 does not propose to amend section 24(a). And we urge that every effort be made to keep such language out of any legislation that Congress may pass to amend FIFRA lest such language endanger favorable prospects for the bill.

We are particularly concerned about several aspects of S. 2621 which go beyond the provisions concerning State authorities in the House bill.

First, S. 2621 would apply to both agricultural and nonagricultural pesticides. That just very dramatically increases the universe of potential State data requests that EPA could be asked to adjudicate.

Second, S. 2621 would prevent political subdivisions in States from regulating pesticides or taking enforcement action on pesticide misuse.

We are a little unsure about the effect that this language might have on the rights of localities to, for instance, license professional applicators or the authorities of county agriculture commissioners.

Once again, I believe that this law should not limit the discretion of the authorities at the State and local level. We, EPA, are not in the best position to dictate how State authorities are distributed and I think that these kinds of decisions are best left to the citizens of each State to make for themselves.

Before I close, Mr. Chairman, I would respectfully urge the committee to give priority attention to the reauthorization of the Scientific Advisory Panel. As you know, the authorization for the Panel lapsed last summer due to the ongoing debate on other amendments. The Agency has found the Panel to be a valuable and integral part of the scientific decision process, and we are ready to appoint new members as soon as the statutory authorization is restored.

I might add that earlier this year we promulgated proposals for how to implement the amendments in FIFRA which required us to utilize a Scientific Advisory Panel to review our decisions.

Now, this concludes my prepared remarks, Mr. Chairman. I would be very happy to answer any questions you may have.

The CHAIRMAN. Thank you, Dr. Todhunter. I do have a few questions but before going to those, I think I should say for the record the committee also has before it the basic question of reauthorizing FIFRA for the next 2 years. We do not need to get into the reauthorization question in any detail at this moment, but the Chair would ask you to provide a report to be inserted in the record to provide the committee with detailed and up-to-date information regarding the obvious budgetary matters. I will give you a copy of what we suggest, and we will insert it in the record as if read. However, in the interest of time, I will not take the time to read it now.

Dr. TODHUNTER. We will certainly provide the information.[1]

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[1] See p. 6

The **Chairman**. Thank you, sir.

The first question, let us look at the provision in S. 2620 regarding the release to the public, and I think this is a term of art definition, of innovative methods and technology. Will you summarize briefly, precisely, in your judgment, what this would do?

Dr. **Todhunter**. In our judgment, it would allow us to better focus the language that was in the section 10 legislation, as amended back in 1978. As you know, there have been continuing disputes over the implementation of that portion of FIFRA. It was felt by us that the process would be speeded up if we could get a better definition or focusing of what, in fact, is an item of innovation, an item of proprietary business information that is distinct from actual health and safety data.

It is our belief that the language proposed here would allow us to provide access to that information, and would merely provide some control over the reproduction of that information in the way of publication, which we feel would markedly bring down the probability that this innovative information could be lost to foreign competitors.

The **Chairman**. It would not inhibit peer review?

Dr. **Todhunter**. No, we do not believe it would.

The **Chairman**. It would not prohibit scientists from communicating with each other, would it?

Dr. **Todhunter**. No, scientists have many modes of communication. One of the most important is mouth to mouth. Scientists talk to one another. There have been some concerns raised over the importance of publication per se as a scientific communication. Scientists do communicate by way of publication; however, usually because of delays in getting things into a journal it is a long process and the information is quite stale scientifically by the time it gets out. We feel the most important mechanism to protect in this regard would be the ability of scientists to talk to one another.

The **Chairman**. I guess what we are talking about is the broad matter of the ability of the scientific community to evaluate registration data required from EPA.

Do you have anything further that you would say in addressing that general subject?

Dr. **Todhunter**. I think that the language which is expressed contains provisions to allow people to see these data, to actually review them. The only controls which appear to us are those on the nature of further publication of such information. I do not think that this bill would at all impede the public's access to this information. I think, if anything, it will help it along because we will have a very orderly process for doing it.

The **Chairman**. What has EPA been releasing under the present law?

Dr. **Todhunter**. We have been releasing things in response to Freedom of Information requests. We have received some small Freedom of Information requests which we have sent out quite promptly. We have also received some very large ones which we are in the process of processing.

The **Chairman**. So, obviously, you agree that there is a legitimate interest in providing an additional level of protection from unrestricted public disclosure?

Dr. TODHUNTER. The administration was somewhat concerned over escape of domestic technology to foreign competitors.

The CHAIRMAN. Just so I can understand the provisions of my own bill, how much of a change, really, is involved in this amendment from the current law?

Dr. TODHUNTER. I believe it is less a substantive change than it is one in terms of defining for the first time what would be done with the information once it is in hand. And it defines better for the first time what sort of things might lead a person to discover process information, which is, as we understand it, restricted under the present law, but is not well defined under the present law.

The CHAIRMAN. So, in a nutshell, anyone having access now will not be prevented from having access under the amendment?

Dr. TODHUNTER. No, certainly not.

The CHAIRMAN. One final question. Does EPA have a position on the issue of adding private right of action authority to FIFRA?

Dr. TODHUNTER. We have stated our position on the House side on this, and this has always been that it is something we feel people have under existing laws other than FIFRA and our preference would be not to see FIFRA cluttered up with additional amendments putting those particular things in FIFRA.

The CHAIRMAN. The staff advises that Senator Huddleston wants to submit a question for a written response, which will be done. And the Chair would mention that any other Senator will have the privilege as well. I know you will be happy to respond to questions from them as well. (See p. 8.)

Doctor, I appreciate your coming. We will be in touch as things develop.

Thank you.

Dr. TODHUNTER. Thank you for receiving our position, Senator.

[The following letter was received by the committee:]

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., July 12, 1982.

Hon. JESSE HELMS,
Chairman, Committee on Agriculture, Nutrition, and Forestry,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: As a result of the hearings before your committee on June 21, 1982, you requested some additional information concerning our pesticide program. I am pleased to provide the enclosed answers to four specific questions for inclusion in the hearing record.

Another issue that we did not specifically discuss during the hearing is that of the "principles" which appear in the version of §10 in H.R. 5203 but which are omitted from S. 2620. I would like you to be aware that the Agency strongly supports those principles, and would urge that they be introduced in the Senate amendment to §10 or, at the very least, be made part of the Committee report.

If I may be of further service, please let me know.

Sincerely yours,

JOHN A. TODHUNTER, Ph. D.,
Assistant Administrator for Pesticides and Toxic Substances.

Enclosure.

[Questions submitted by Senator Helms and answers thereto:]

Question 1. The Agency's proposed pesticide program budget, including research and development activities, for Fiscal Years 1982 and 1983?

Answer. Our current estimate for fiscal year 1982 is $53,738,100 and for fiscal year 1983 $50,782,000.

Question 2. The impact that adoption of the amendments in S. 2620 and S. 2621 would have on the Agency's budget, if any?

Answer. The Agency does not anticipate modifying its budget request in light of the pending amendments. However, if the bill passes, EPA will obviously need to devote resources to implementing its provisions. This will entail writing new regulations for §3 and §10, and devising a new data compensation system and incorporating it into the registration process. The data index and its computer support will need to be developed. Procedures for adjudications under §3 and §24(a) will need to be developed. These tasks will of necessity be done in lieu of some of those activities for which we've already budgeted.

Question 3. The Agency's activities over the last year in the areas of (a) registration and tolerances, (b) standards setting and RPAR, (c) federal and state program support and (d) pesticide enforcement?

Answer. (a) In Fiscal Year 1981 the Agency conducted 142 reviews of new chemicals, including 27 biorational pesticides. In terms of program and budget planning, reviewing data is our principal activity, but it is not the equivalent of registering a product. A data review leads to a decision point which may be to register the chemical, or to require further action from the applicant. Thus, the number of new chemicals registered in fiscal year 1981 was 20 including 6 biorationals. The Agency conducted 7,673 reviews of old (already registered) chemicals, of which 2,350 resulted in product registrations. 22,736 amended registration reviews were processed, which included label amendments and distributor registrations. The Agency conducted 371 tolerance petition reviews, resulting in the establishment of 98 tolerances or exemptions from tolerance requirements.

The Special Registration program performs auxiliary functions to the registration process by: issuing Experimental Use Permits (EUPs) to allow the development of data needed for registration; establishing temporary tolerances to allow marketing of crops treated with experimental products; granting exemptions to states or other Federal agencies to use pesticides for nonregistered uses in emergency situations; and reviewing state registrations of pesticides to be used only within the registering state to meet special local needs. In FY 1981, the Agency conducted 434 reviews of EUPs, 109 reviews of temporary tolerance petitions, 450 reviews of emergency exemption requests, and 1,424 reviews of state registrations.

(b) In FY 1981, the Agency completed 18 Registration Standards. The Agency initiated a data call-in program to obtain long-term health effects data on chemicals for which standards had not been started. Data call-in ensures that these critical data will be availble by the time standards are ready for development. In 1981, the Agency reached final resolutions for 11 RPAR chemicals. This includes three cases in which companies voluntarily withdrew their chemical from the market after negotiation with the Agency.

(c) The Agency's program of Federal and State Program Support includes consultation and the exchange of information and technical advice between EPA and Federal, state and local officals with interests in pesticide regulation, as well as assistance to pesticide users, pesticide producers, and the general public. Information and referral services are provided to government agencies at all levels, trade organizations, poison control centers, hospitals, physicians and worker clinics dealing with pesticide problems. In FY 1981, $697,000 were obligated for these activities.

(d) The Pesticide Enforcement program includes monitoring the pesticide industry-producers, distributors, and users—for compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); providing compliance assistance to the regulated community and when necessary, issuing notices of violation and administrative orders. Also included in the enforcement program is the management and funding through grants of state cooperative enforcement agreements and state certification and training programs for pesticide applicators.

In FY 1981, the EPA compliance monitoring program accomplished 287 inspections of pesticide producing establishments, 485 use and reentry inspections, 241 inspections at ports of entry, 291 marketplace inspections and 4 laboratory audits. As a result of these and states' efforts, the Agency issued 154 administrative orders for product/producer and use violations.

In FY 1981 the Agency obligated $8,013,500 for cooperative enforcement agreements with 51 states and territories. This funding provided resources for states to conduct 2,538 establishment inspections, 10,436 use and reentry inspections, 7,171 marketplace inspections, 10,928 applicator license and record inspections, and 6,737 dealer record inspections.

The Agency also obligated $2,951,000 for funding applicator certification and training programs in 52 states and territories.

[Question submitted by Senator Huddleston and answer thereto:]

Question. To what extent does S. 255, the Patent Term Restoration Act, conflict with or overlap with the exclusive use provisions of S. 2620?

Answer. There appears to be no inherent conflict between these two forms of protection. The basic thrust of both is to provide a reasonable and consistent period of protection based on the time when the regulatory decision has been made and marketing can begin. For new chemicals, the patent term and the period of exclusive use will most likely run concurrently.

The CHAIRMAN. Next on the agenda is a panel consisting of Doctor Early—and I will ask the gentlemen to sit on this side. Jack Early, president of the National Agricultural Chemicals Association; John Wise, president of the Pesticide Producers Association; Edgar Duskin, Southern Agricultural Chemicals Association of Dawson, Ga.; and Ralph Engel, president of the Chemical Specialties Manufacturers Association. Gentlemen, we welcome you.

I would mention for those having prepared statements that the entire statement will be inserted in the record as if read. If you so desire, you may summarize your statements and we will get to the questions. It is entirely up to you.

You may proceed, sir.

STATEMENT OF JACK EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Mr. EARLY. Thank you, Mr. Chairman. We have submitted to the committee a rather lengthy written statement.[1] And we have taken the liberty to try to summarize this lengthy written statement down to what we think is an appropriate amount to deal with this afternoon before the committee.

I thank you, Mr. Chairman, for the opportunity to be here today. As you indicated, I am Jack Early, president of the National Agricultural Chemicals Association. NACA is an association of nonprofit trade organization of manufacturers and formulators of pest control products employed in agricultural production. NACA's membership is composed of the companies which produce and sell virtually all of the technical crop protection chemicals and a large percentage of the formulated products registered for use in the United States.

I am appearing as a member of this industry panel today, as you have indicated, and I am looking forward, as you are, to the comments from my colleagues.

Mr. Chairman, NACA supports the passage of S. 2620, and would like to commend you, Mr. Chairman, for introducing a bill that has addressed the concerns of our industry and of other concerned groups in a balanced way. Although this bill is basically similar to the bill reported by the House Agriculture Committee, it makes a number of constructive changes and improvements which I believe are important to our industry and to the agricultural community.

Essentially, this bill represents several compromises worked out between all segments of the pesticide industry, the agricultural community, user groups, environmentalists, labor organizations and the Environmental Protection Agency. No one group has been able to obtain all of the changes it wanted, and certainly there are many ways in which NACA would like to change the bill to meet all of the desires of our members. But, in the end, the important fact is that this bill reflects a workable compromise—a compromise that accommodates every group's principal and legitimate concerns, and a compromise that our industry is satisfied with.

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[1] See p. 89 for the prepared statement of Mr. Early and p. 96 for a followup letter from Mr. Early in response to questions raised at the hearing.

In my testimony today, Mr. Chairman, I would like to address two of the principal changes to existing laws made by this bill that are of most concern to NACA. I will leave the discussion of other aspects of the proposed legislation to my colleagues here on the panel.

Our overriding concern and the reason why our industry has pursued these legislative amendments so vigorously over the past 2 years is to preserve the economic incentives for the pesticide industry to invest in research and development. The benefits of this research transcends our industry.

These innovative efforts benefit the agricultural community and the public by providing a wider variety of safer and more effective crop protection chemicals that increase farmers' crop yields and profits; lower agricultural production costs and reduce the risk of human disease caused by pests.

Today, less than 3 percent of the U.S. population feeds us and much of the rest of the world. In 1980, exports of agricultural products contributed almost $40 billion to our balance of payments. Throughout the world, however, losses of food to pests are enormous. Agricultural chemicals significantly reduce but do not eliminate pest losses. The use of agricultural chemicals increases the quantity of our food. It also can improve food quality by reducing contamination in pest-induced toxins.

Innovative research and development of newer, safer and more effective products and uses is perhaps the most important factor behind this country's success story in the field of food production. Innovative research, however, must be supported by realistic economic incentives.

On an average, it now takes some $20 million to $25 million to bring a new product from discovery through the registration process at EPA. The time from discovery of the pesticidal properties of a compound until a new product can be marketed is in the neighborhood of 8 years. The construction of a new chemical plant to produce and manufacture a new chemical adds an additional cost of some $40 million to $70 million. These costs are incurred before the product enters the marketplace and without any assurance of commercial success for the companies who have borne the risk of this research.

The product of this multimillion dollar research investment is contained, to a large extent, in the research data which include information on effectiveness, safety and properties of the pesticide. Much of these data are required to be submitted to the Environmental Protection Agency for registration purposes.

To maintain incentives for research, these research data must be protected against exploitation by competitors who have not borne the risks, expense or effort involved in generating this proprietary information. Unfortunately, changes were made in FIFRA in 1978 and eliminated much of the proprietary protection for such data. Those changes made it possible for competitors to use these research data for Federal registration purposes without adequate return to the data owner.

The unrestricted disclosure provisions of that law made it possible for a competitor to obtain a copy of multimillion dollars worth of research data package from EPA and to use this information to meet foreign government registration requirements and to glean valuable innovative scientific methods and proprietary information discovered by the data developer.

S. 2620 remedies these defects in a number of important ways. Amendments to the so-called exclusive use provision of section 3 provide that for a period of 15 years, competitors may not use data developed by an innovative company which concerned new chemicals or new uses for the purposes of registering their own product.

Like H.R. 5203, S. 2620 increases the period of data protection from the existing law from 10 years to 15 years. This change greatly enhances the incentive for innovative research. The Senate bill makes a significant improvement over the House version by also providing 15 years of protection for a wider variety of data that concern new uses of pesticides, thus providing stronger incentives for research to expand the uses of existing chemicals.

Without such incentives, research to register minor uses to satisfy specialty crop pest control needs might not be performed.

A second major change in existing law in this bill is to close off access to these valuable research data by competing pesticide companies under the Freedom of Information Act, preventing competitors from using the data for foreign registration purposes or exploiting the scientific discoveries and innovations made by the data developer will help preserve the incentive to perform the research. It is important to point out that this bill protects the competitive value of scientific information on pesticides without restricting access to health and safety data by interested members of the public, such as environmental, labor, and public interest organizations.

The bill assures members of the public full access to health and safety information, including innovative scientific methods so that they may monitor EPA's pesticide decisionmaking. The proposed legislation does, however, place controls on the copying and transfer of data and on persons given access to innovative methods to insure that the data are not improperly given to competitors, such as pesticide producers and registrants who could use the information for commercial purposes.

The bill also creates severe penalties for industrial spies and others who violate the disclosure restrictions to gain competitive advantage.

While NACA members would undoubtedly prefer even tighter controls to better guarantee the valuable research data will not be disclosed to or used by competing businesses, we are satisfied that the controls established in this legislation, once it is effectively implemented by EPA regulation, should reduce the prospects of competitive harm from disclosure of this information.

Mr. Chairman, we appreciate the opportunity to acquaint this committee with our views concerning data protection. And this concludes our oral remarks. We will be pleased to respond to any questions.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Early.

Identify yourself for the record and proceed, sir.

STATEMENT OF JOHN WISE, PRESIDENT, PESTICIDE PRODUCERS ASSOCIATION

Mr. WISE. Mr. Chairman, my name is John Wise. I am current president of Pesticide Producers Association.[1]

The Pesticide Producers Association is a group of small regional formulators and manufacturers of pesticide products. We are primarily serving markets that are designed around States or southern regions of the United States across this country.

The Pesticide Producers Association is, as I stated, primarily formulators. We are interested in being able to maintain into a market and in such competition with the basic producers where this may come about.

We support the passage of S. 2620. We have reviewed this bill and have found it to meet most of the needs that we have.

Many of the things, as Dr. Early has stated, are not completely agreed upon by all sides. But we have worked together for many months to work a compromise out that we feel will create competitive interests needed in today's marketplace to allow all people to compete in this pesticide business in the United States.

We recognize several things:

One, that without innovative work being done by the basic manufacturers and researchers in this country, the formulator would not exist. In this aspect, we believe that by extending the 15 years protection allowed in the section 3(c)—I am sorry, 3(h) area, exclusive use for new compounds and new uses will provide incentive necessary for them to continue doing research and development needed by the agricultural community.

At the same time, the changes being made here do not block or prevent a small formulator from entering into any one of these markets if he so chooses to either work directly with the basic producer in obtaining the use of that data or by either producing his own data.

We support changes in the section 3(c)(2)(D) area on the formulator's exemptions. The changes made in S. 2620 provide that the formulator is basically exempt from production of most of the long term expensive toxicology data that is based around the technical chemical itself rather than the formulated product.

By exempting the formulator from production of this data, it allows him to enter into the market and to compete. This data is the data that is necessary to register technical products, products that are primarily produced by the basic producers or other manufacturers which are sold to the formulator and which is used for the purposes of creating the formulated products to today's market.

Since this data is being generated on the technical chemical, we feel that by exempting the formulator from the requirement of producing this data will allow him into the market and still be able to protect the rights of the basic producer.

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[1] See p. 99 for the prepared statement of Mr. Wise.

We are supporting the changes in section 3(c)2(B) on the defensive data. This data is data that is required by the Environmental Protection Agency to continue the registration of existing pesticide products.

We believe that the changes being proposed in S. 2620 will provide the necessary incentives for those companies involved to develop the data, by sharing the costs based upon their market size. We feel that this is important because it does not block any one company from entering into a market and a competitive situation on an unpatented compound.

I would like to briefly address also S. 2621, section 24(a). We support the changes in section 24(a), as contained in this bill far beyond those that are supported under H.R. 5203. The reason being that H.R. 5203 that is being proposed in the House at this time does not provide any protection to the agricultural chemical market.

We feel that it is important that the agricultural chemical market be able to function within the States because this is the prime objective that pesticide chemicals are being used toward.

As Dr. Early has stated, it is important that we support agriculture, the 3-percent population that we have producing the entire abundance of food being used in this country today.

Section 24(a) amendments will keep States from making arbitrary and capricious requests for data that are unnecessary. To give you some examples of this: We currently have members of our association who have found problems in registering compounds within the States who have requested additional data. One of our members had under the current FIFRA offered to pay data compensation, had met the requirements and obtained registration. The State had requested that they also supply the data to the State for their review, even though the product was federally registered. The company was unable to do so due to the fact that this data was held by the generator of the data within EPA files, and it was not made available to them in hard copy form. They have been unable to register their product in that State.

The changes in 24(a) and section 10 will allow this to be done. The State may request that data be transmitted to them from the EPA.

Another one of our companies is involved in a situation where they had a product registered in the State of California prior to the time when the new regulations in California came about. Since that time, they have upgraded their label, added new uses and new precautionary statements to it. Their statement has been approved by EPA. However, the State of California will not at this time allow them to register or use that label within the State due to the fact they cannot supply all the data to support it, even though the Agency is perfectly content with the fact the product is safe and meets all of the requirements of Federal law.

This company is required now to provide two products, one for the rest of the United States and one for the State of California. And it is questionable whether the State of California label is legal under the Federal law while it is legal under the State law.

We have had problems repeatedly with obtaining data for the registration within States. Formulators are not generally the producers of data, as we said before. We rely upon that work that is done by the basic producers and researchers in this country. This data is important to be able to transmit it to the State and, at the same time, keep the States from making arbitrary and capricious requests for data that is unnecessary, that data which is in the Federal files and for which the Federal Government under EPA's auspices has found to be safe and efficacious under the current law.

I wish to thank the Chairman for this opportunity and will open up to any questions he may have.

The CHAIRMAN. Thank you very much.

STATEMENT OF EDGAR DUSKIN, EXECUTIVE VICE PRESIDENT, SOUTHERN AGRICULTURAL CHEMICALS ASSOCIATION

Mr. DUSKIN. Mr. Chairman, I am Edgar Duskin, exective vice president of the Southern Agricultural Chemicals Association.[1] We cover 13 Southern States as an independent regional trade association. North Carolina happens to be one of our States, naturally.

Some of our members, we have some of the same membership on a regional basis, are members of the National Agricultural Chemicals Association and of the Pesticide Producers Association.

The bulk of our membership comes from the independent, either regional or intrastate formulators and distributors of pesticides. Take, for example, Meherrin Chemicals in North Carolina, Cardinal Chemical, J. C. Whitehurst of Coastal, and some of those as examples of types of companies that are members of our association throughout the South.

Their basic problem is that they simply want to be able to buy their technical pesticides at the best possible price, with the data that is necessary to register them. They do not want to get involved in controversy about data compensation or other issues. They would simply like to buy it, manufacture their end-use product and be allowed to sell it to the farmer at the best possible price. And part of their function, of course, is providing service as well.

The high interest rates and thin profits this year emphasize the problem within this small segment of the area.

Compromise among industry factions and a better understanding and less antagonistic approach from EPA is the best thing that can happen to our segment of the industry.

We have supported compromise on all the items of section 3, section 10 and all the others that will serve to get on with the registration process and get products in the field. The innovative ideas, either for new uses and certainly the basic companies coming out with new products, is where the profit is for the distributor. Where everybody has a product on the market, the competition is such there is just no margin. When new products come along there is a better chance for a man to sell and do a better job and get the product out.

We are the first to support any measures that will spur innovation. We need them all the way down the line.

We have several problems with some of the things that go along with the pesticide bills proposal. As I said, we support the changes to section 3 and section 10. They are companions. They go hand-in-hand. We support the compromise that has just been worked out on the "new-use" definition. We like the "three clock" idea. We have quite a few of our members who prefer that there be no restriction—no compensation or exclusivity on new uses at all. We are first to admit that. In order to get something that we can all live with, the idea they have come up with on new uses, we believe is workable and acceptable if someone does not rock the boat with lawsuits over vague language. We do not believe that will happen. We certainly hope not. This will simply muddy the water for all of us.

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[1] See p. 105 for the prepared statement of Mr. Duskin.

We are not testifying tomorrow concerning S. 2621. However, in our statement we have made some remarks concerning it. Fundamentally, we support the provisions of S. 2621. We believe, being from Southern States particularly, we are the strongest believers I guess in States rights of anybody, but we think there is a limit. And we believe the State should be able to ask for anything it needs, but not on a capricious basis, and not for the purpose of stalling registrations by asking simply for more data. We believe if data is good enough for Federal registration, unless there is some peculiar need in that State, it ought to be good enough for a State to accept it. It should have access to the data if it needs it for some purpose. No one argues this. It is just a question that we are continually faced with people asking for more, different data and it becomes a stall, rather than what we consider to be a legitimate requirement. This is in a very, very few States, and this is where we have our own fundamental difficulty. And we support States rights.

There are some other provisions that have been in and out of the House bill. I think Mr. Todhunter referred to them briefly. We also feel they will simply clutter up this bill. We believe we need to get a bill quickly that accomplishes and satisfies the fundamental requirement and go with it and work the others out.

Thank you.

The CHAIRMAN. Thank you, sir.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

Mr. ENGEL. Mr. Chairman, my name is Ralph Engel. I am president of Chemical Specialties Manufacturers Association.

I am due to testify tomorrow principally on the issue of 2621 and 24(a), but, with your kind indulgence, I would like to make one remark, if I may.

The CHAIRMAN. Please proceed.

Mr. ENGEL. And particularly in light of what EPA has indicated and what some of my colleagues have indicated, we too recognize that the administration is indeed committed where appropriate to a policy of deregulation and a shift of more regulatory responsibility to the State level. The administration is and has to be keenly aware that there are areas of regulation that require Federal responsibility and coordination.

Any areas that affect interstate commerce and technical standards which have a national if not international, significance are areas which require Federal leadership.

Currently in California and certain other States, they wish to conduct scientific evaluation above and beyond that conducted by EPA prior to issuing a State registration. Such a separate evaluation can lead to a decision not to allow the use of an EPA-registered pesticide or to require conditions of use different from that permitted by EPA.

This kind of divergence in registration practice would lead inevitably to serious problems that would adversely affect the public. Indeed, if each State conducted its own scientific evaluation for registration, there would be no need for EPA to do the same. FIFRA would be meaningless if the States could, by the nature of the system, continually overrule the Federal standards.

It is EPA's responsibility under FIFRA to register pesticides on a national basis without arbitrarily imposing Federal standards on the States. To that end, Mr. Chairman, our industry appreciates this opportunity to comment on the Senate FIFRA legislation. We believe the best approach for the committee is to combine S. 2620 and S. 2621 into a single bill.

The 24(a) provision as it evolved in the House and as modified in S. 2621 is a compromise which we feel would go a long way toward assuring the continuity in processing of applications and requests for additional data at the State level.

Thank you very much for your time, sir.

The CHAIRMAN. I thank all four of you. All of you have testified before the committee before and you understand the necessity at times for being repetitive for purposes of the record.

Some of the questions that I will ask will appear or, indeed, be repetitive.

Mr. Engel, your organization represents a significant segment of the pesticide industry. I think it would be appropriate at this point to have you elaborate on what you just said. That is, what is your analysis of the need for the amendments in S. 2620 regarding registration procedures and the disclosure of data generally?

Mr. ENGEL. That would be in S. 2621?

The CHAIRMAN. S. 2620.

Mr. ENGEL. I am sorry, sir, could you go back?

The CHAIRMAN. The staff advises me that you had some relevant comments about the need for the amendments in S. 2620 regarding the registration procedures and disclosure of data generally. And I thought it appropriate, since you had just finished, if you wanted to elaborate, this would be the time to do it.

Mr. ENGEL. Thank you, sir. I think these gentlemen probably have covered it as broadly as could be possible.

The CHAIRMAN. Very well.

Mr. ENGEL. We do want to tell you though we do support S. 2620 and its contents.

The CHAIRMAN. Very well.

Now, Dr. Early, we will go back to the head of the line, just briefly.

Dr. EARLY. Yes.

The CHAIRMAN. I would like you to elaborate on the provision in S. 2620 granting additional protection to information which a company claims to contain innovative scientific methods and technology.

Now, how would you envision that this information would be made available to independent scientists, operating outside of EPA for the purpose of conducting a peer review?

Dr. **Early**. I would be glad to comment on that, Mr. Chairman. We heard Dr. Todhunter speak to that a little earlier this afternoon.

Let me make this opening comment. My industry feels very strongly that innovative methodology, this type of research that we are talking about here, at the outset really should be classically considered to be trade secret information. And our preference is that none of this information should be made available to anyone outside of EPA who makes the regulatory decisions. But, in the spirit of compromise, and recognizing the open society in which we live today and the right of the public to look at the health and safety information, we have agreed that we would put what we call innovative methods into what we call a special category. This is a category whereby it does not enjoy trade secret status but it does enjoy some degree of protection in that it allows independent scientists to come in and request to look at innovative methodology. They can look at it. They can share this information with qualified scientists. The information can even go to the Scientific Advisory Panel of EPA. We therefore can really have a clear peer review of innovative methodology.

There is something else that has not been brought out here. The statute calls for only a 5-year period of protection of innovative methodology. Once the 5-year period is gone, the information falls into the classic area of health and safety data. So you only enjoy a short period of time to protect an innovation.

As an example: Suppose you, as a company, developed a new radio chemistry method for detecting residue in plants, and no other company was aware of this technique that you had developed, but this technique would be of value to X company. We do not think it is appropriate that EPA or anyone should share that information with a competitor to give him an advantage that would allow him to move into the same area of chemistry and use some of these techniques that have been generated by the original company.

So it is just this kind of information that we believe ought to enjoy a special category for at least a short period of time before it is made available to the general public as is the case of health and safety information. But the scientists in the public interest groups do have access to it. And also I think it is appropriate that only scientists look at this information, as opposed to someone on the street who maybe does not understand some of the intricacies of this scientific information.

If I were to sit down and look at these volumes of studies—and we have 12 feet of them—I would have a great deal of difficulty understanding some of the information that is in there. And, without being too presumptuous, Mr. Chairman, you would probably have some of the same trouble. So I think we need to put this information in the hands of those people who are best qualified to make a valued scientific judgment.

The Chairman. Even at best, however, it is going to be a tough judgment many times as to whether the competitor is be:ing served or the advancement of science is being served.

Dr. Early. It has been a very difficult area to strike a balance and I am sure you can appreciate that from the testimony.

The Chairman. I can indeed.

Let me make this suggestion: I think we have covered everything that I had on my list. Rather than chasing the dog around a tree right now with the rest of these, let us examine to see if there is any further relevant questions and we will submit them in writing to you and you can submit your answers in writing and save everybody a little bit of time.

Dr. Early. We would be delighted to do that.

The Chairman. Thank you very much. Does anybody have any further comment? Thank you very much, gentlemen. We appreciate your coming.

Our next witnesses consists of a panel, including a distinguished member from North Carolina, Dr. Frank Guthrie, North Carolina State University; Jacqueline Warren, representing the Natural Resources Defense Council, and Jay Powers, representing the AFL-CIO. If you folks will come forward.

While you are coming forward I am going to make a telephone call that will take less than 2 minutes, and I will be right back.

[A short recess was taken.]

The Chairman. The committee will come to order again. We welcome all members of this distinguished panel.

Mr. Shorey, as I understand it, is an attorney for the March of Dimes. I am going to defer to you and let you present my fellow North Carolinian.

STATEMENT OF CLYDE SHOREY, VICE PRESIDENT, PUBLIC AFFAIRS, MARCH OF DIMES

Mr. Shorey. Thank you, Mr. Chairman. I am Clyde Shorey, the vice president of the March of Dimes for public affairs. The principal objective of the March of Dimes is the prevention of birth defects. And, in seeking to accomplish this objective, we are eager to prevent the licensing of pesticides or any other chemical which can cause birth defects.

We are concerned that the proposed amendments would substantially weaken the review process to determine the health effects of pesticides and we, therefore, asked Dr. Frank Guthrie to appear before this committee to discuss this issue with you.

Dr. Guthrie is a professor of an interdisciplinary program in toxicology at the North Carolina State University, where he has been in residence since 1954. He has had recent work in pesticides relating to pesticide residues on tobacco, pest management, insecticide resistance, subcellular location of insecticides; absorption of pesticides, blood transport of insecticides and the hazards of reentry into previously treated fields.

He currently teaches two courses in insecticide chemistry and two courses in toxicology. He is a member of the Society of Toxicology of the American Chemical Society and of the Entomological Society of America.

He is on the editorial board of Environmental Health Perspectives and the Journal of Toxicology and Environmental Health.

He has been a consultant to the United Nations and the National Institute of Environmental Health Sciences and to the President's Committee on Environment.

He has published approximately 100 research articles in peer review outlets and is a coeditor of two textbooks on toxicology.

Dr. Guthrie.

The CHAIRMAN. Doctor, what do you do in your spare time?

STATEMENT OF DR. FRANK GUTHRIE, NORTH CAROLINA STATE UNIVERSITY, ON BEHALF OF THE MARCH OF DIMES

Dr. GUTHRIE. Mostly read. The only thing I might add to that is that I was on the advisory committee that awarded Mr. Early his Ph. D. degree, which I might want to take back before this is over.[1]

My comments are directed to the proposed amendments in H.R. 5203 or 2620, and specifically to the changes proposed for section 10(d) concerning innovative methods and technology, which I still do not quite understand.

The problem that specifically concerns me regards birth defects possibly caused by chemicals in the environment. The scientific explanation for birth defects is in its infancy. The U.S. population was largely spared the unanticipated and tragic events following the use of Thalidomide. This event did, however, serve one important cause to this Nation. It clearly demonstrated that chemicals could cause birth defects and that chemicals were not then receiving adequate scientific scrutiny for possible birth defects.

A considerable effort has now been mounted in the United States to avoid a repeat performance.

Such research is painfully difficult and slow to accomplish—and I have listed some reasons for this. The scientific community can ascertain at the present time the anticipated results of larger doses with some certainty, but the "unanticipated" effects are more difficult to ascertain.

Every attempt possible must be made to circumvent such untoward possibilities. Additional scrutiny, not less scrutiny as proposed by this bill's amendment, seems in the public interest.

If industrial companies are permitted the luxury of concealing facts learned from innovative methods and technology to a segment of the public, one additional safeguard has been removed. Such restrictions cannot possibly aid the discovery of health hazards of chemicals, and it certainly might decrease the possibility of detection of an unanticipated effect at an earlier date.

Obviously, no chemical company and no legislative body wants to be a party to accidental release of a chemical which might cause a birth defect.

For these reasons and those listed in my testimony, I recommend that section 10(d) be modified to include availability of testing data to all segments of the general public to maximize scientific scrutiny of chemicals which might cause birth defects.

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[1] See 106 for the prepared statement of Dr. Guthrie.

The CHAIRMAN. Thank you, Doctor. I would add that all prepared statements will be printed in the official record of the committee.

Next on the list is Jacqueline Warren, representing the Natural Resources Defense Council.

STATEMENT OF JACQUELINE WARREN, REPRESENTING THE NATURAL RESOURCES DEFENSE COUNCIL, NATIONAL WILDLIFE FEDERATION, AND ENVIRONMENTAL DEFENSE FUND

Ms. WARREN. Thank you, Mr. Chairman.

I am speaking today on behalf of three of the Nation's leading conservation organizations: the Natural Resources Defense Council; the National Wildlife Federation; and also the Environmental Defense Fund. All three organizations have followed EPA's implementation of the pesticide law and participated in debates before the House Agriculture Committee.

My testimony is quite lengthy and I am not going to read it.[1] I am going to focus on the major areas of controversy although there are several others that are detailed in the testimony. The obvious major one has to do with restrictions on public disclosure of health and safety data.

It was not that long ago that many of the people in this room were here talking about the very same point, in favor at that point, from our side, of an amendment to FIFRA that would require the disclosure of health and safety data, which had not been made public in the past.

There was very extensive debate in both the House and Senate on that amendment, and it was enacted in 1978. It has never been implemented. Dr. Todhunter said earlier that it seems to be working well but, as a litigant in one case where we found it is not working at all, and have had to sue the Agency to get the data, I can tell you that section 10(d) was held up in litigation from the day it was enacted until just within the past year. The first requests for information under section 10(d) are just in the process of being processed by EPA, and the Agency is not disclosing the data. So we do not have a good history of how well that approach works or does not work.

The legislative history is replete with statements by Senators and Congressmen about how section 10(d) was an attempt to balance the concerns of the pesticide industry for their trade secret interest and their investment, the development of that data, with the right of the public to have the disclosure of whatever studies convinced EPA that a pesticide was not going to harm them or do damage in the environment.

Our position all the way along has been that we would like to give that amendment a chance to work and see if it works, because the arguments for changing it are really based on speculation. It has not been implemented yet so there is not a good history of it.

In the debates before the House Agriculture Committee, the discussion did not deal with adverse competitive impact in the United States because the statute in 1978 provided for the sharing of data development costs for anyone who wanted to rely on someone else's data.

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[1] See p. 108 for the prepared statement of Ms. Warren.

We got to the point of talking about theoretical competition in foreign countries and the question was raised about patents; are they not patented over there? And it turned out that yes, they were patented in many places. And we began to be talking about Brazil and Red China and a lot of very vague "mights" and possibilities and a parade of horribles which was actually brought to this committee's attention the last time around, debated at great length and rejected in favor of an approach which was felt at that time to balance the interests of the competing parties very adequately. We still think that it does balance those interests.

Nevertheless, the House committee was persuaded by the chemical industry's arguments that they made a mistake the last time even though there was not any evidence to support that contention, and some changes were proposed.

Mr. Early said previously that their great compromise on innovative methodology is a retreat from the position that that information should not be available at all. As a matter of fact, current law provides that that information should be available. So their compromise is really not a compromise at all, because they are simply gaining some more protection than current law gives them.

We engaged in negotiations in an attempt to try to get the provisions as workable as they could be and without taking too much away from us.

Some of the parties negotiated and we reached a partial compromise. We never agreed on the innovative methodologies provision. It remains very controversial right now, as you have heard and will hear from other witnesses. But we did agree on a set of principles to implement the part of the compromise that we agreed on. And that set of principles is absolutely integral to whatever agreement existed. That set of principles would be right in the statute in the House bill. It is not in the Senate bill. It is not even referenced in the Senate bill. So, as far as I am concerned and the other parties on our side of the table, there is no more compromise. There is no more agreement because the part of the bargain that we thought we were getting out of that compromise is not in this bill.

Having said that, I would like to address the innovative methodology question more directly.

The statute provides for compensation by people who want to rely on somebody else's data. So, to the extent that a chemical company invests in an innovative methodology, they will be compensated if somebody else relies on it. That person cannot get a registration in the United States.

The innovative methodologies deal with the environmental fate of pesticides. That is the one area where we do not really know that much about pesticides. It is a question of exposure. Where does the pesticide go in the environment, and how are people getting exposed to it.

This provision places a 5-year imposition on peer review. Regardless of what Dr. Todhunter said, peer review is a lot more than simple discussion between a few scientists who happen to find out and get access to the information. It is a matter of open discussion in the scientific community, replication of studies and confirmation of results. That is not going to happen with innovative methodologies that no one knows exist because the whole process treats them, in effect, as if they were trade secrets. The fact that access for some of the parties around the table, labor, environmental and a few health organizations and migrant legal action organizations, is written into the bill is a reflection of who was at the table that day. It does not necessarily cover the spectrum of members of the public who might be interested.

The bottom line really is that we believe that a heavy burden of proof should be borne by a party who is advocating a change in the law. And particularly when the provision they want changed has no history of implementation. We do not believe that the chemical industry has met that burden with respect to innovative methodologies or the other changes they are proposing for section 10.

The innovative methodologies exemption from disclosure could take in a very large body of information. Scientists that we have shown the provision to do not understand what it would cover, and we do not understand what it would cover either, and we urge the committee to strike it from the bill.

There is another point in the section 10 amendments which has to do with the private right of action by one data submitter against another for treble damages for violation of regulations that would govern the disclosure of data.

We asked for a private right of action. We are not getting it. The chemical industry asked for a private right of action and they are getting it with treble damages plus attorney's fees.

They stated that a private right of action for farmworkers amounts to cluttering up the statute with amendments. I would challenge whether anybody in this room could read the section 3 amendments that are in this bill, first of all, and understand them and, second of all, really answer the question whether that is cluttering up the statute otherwise than affirmatively.

The provision with respect to civil action and treble damages says anyone who violates—"wilfully violates for a commercial purpose," could apply to a scientist who gets a fee for an article on something to do with the data that is a perfectly legitimate use of that data.

The point of the treble damages provision is to deter misuse of the data by pesticide competitors. And in a separate section of the bill which deals with penalties, it says "for a commercial purpose involved with the production, distribution, registration of the pesticide." We urge that if this provision stays in the bill that the commercial purpose language be tailored specifically to the abuse that was apparently intended, which is the misuse of the data by a competitor. As it is now, it is really going to deter anyone who gets the data from doing anything with it for fear of being hit with a treble damages suit because they accepted a fee for writing an article and somehow or other infringed on the regulations, which are not well defined as to what they are supposed to cover.

There is one other matter that I would like to address which has to do with the Federal preemption of State pesticide regulations. Congress has consistently legislated in the environmental area, expressing a Federal interest in environmental matters, or in matters which affect health and safety and transcend State boundaries. In all of those cases Congress has said, this is the minimum that States must do. They have never said, with the possible exception of atomic energy where the Federal interest in preemption is very clear, they have never said, a State cannot do any more than this.

The provision here we view as a great intrusion on the right of the States to determine what is necessary to protect their citizens within their borders. One example of the kind of problem S. 2621 would create is in the case where a pesticide might contaminate ground water. That has been a problem in California and it has been a problem in New York. EPA does not presently apparently review the mobility of a pesticide through the soil to see whether it is likely to contaminate ground water.

Under S. 2621 the State would have to wait until the damage occurred so they could document with significant factual information that this is a problem of a special local kind for the pesticide.

Regarding the interruption of commerce in pesticides, as an attorney, in viewing the evidence, I do not see the kind of compelling evidence that would justify the Federal intrusion on States rights that that provision represents. It seems to me that the States have traditionally been able to protect the health and environment of their citizens to the extent that they saw fit, and they should continue to be able to do that unless a really compelling case is made to the contrary.

One last point that I would make is that while this bill is giving several new hearing rights to the chemical industry when they are challenging the data submitted by a competitor, and even provides for attorney's fees and a civil damages action, groups like ours, environmental groups, consumer groups, farmer groups are not entitled to ask for hearing at EPA to challenge a pesticide decision. We used to have that right. If EPA made a decision on a pesticide that we didn't think went far enough, we were allowed under section 6(b), as a person adversely affected by that decision, to ask for a hearing.

In 1979, EPA reinterpreted that provision to mean only persons who have an economic stake in the pesticide can be adversely affected by a cancellation decision. We are asking that the standing to participate and to ask for an administrative hearing at EPA be reinstated. It is one more change in the statute. It is not complicated. It is not technical. It will not clutter up the statute, but it will correct an imbalance which is an inequity under current law that, when all the procedural rights are granted to the industry under this bill, will be greatly exacerbated.

We support several other amendments which I have described in my testimony that other witnesses are going to speak about.

Thank you.

The CHAIRMAN. Mr. Power.

STATEMENT OF JAY POWER, LEGISLATIVE REPRESENTATIVE, AFL-CIO, ACCOMPANIED BY PEG SEMINARIO

Mr. POWER. Thank you, Mr. Chairman.

My name is Jay Power. I am legislative representative of the AFL-CIO. I am accompanied today by Peg Seminario of the Health and Safety Department of AFL-CIO.

Mr. Chairman, in the interest of time, our statement is very brief, but I will attempt to summarize it in order to move along with the knowledge that our statement will be printed in full in the record of today's hearing.[1]

The AFL-CIO has a direct and immediate interest in the reauthorization of the FIFRA Act.

Members of the AFL-CIO employees union face serious risk of disease, injury, and death from pesticide use, application, and manufacture. For farmworkers and pesticide applicators FIFRA provides the primary occupational health and safety protection, though that protection is far from adequate. For these and other workers FIFRA also provides the major vehicle for the development of health and safety data on pesticides and access to this information. Thus, the FIFRA Act and its effective implementation are central to protecting workers from pesticide exposures.

Congress has an opportunity to correct many of these deficiencies in the FIFRA Act. But neither S. 2620 nor S. 2621 adequately address these problems. Indeed, in the view of the AFL-CIO their passage would greatly erode the minimal protections provided workers and the public against the hazards of pesticides and thus we oppose both bills. Our specific objections are as follows. And, again, Mr. Chairman, I will attempt to summarize.

No. 1, no private right of action for workers or the public. EPA enforcement of FIFRA, particularly in the area of farmworker protection, has always been dismal. Now with Federal budget cuts enforcement is sure to deteriorate further. A private right of action for workers and the public to seek relief from hazardous pesticide exposures through the Federal courts would provide an independent enforcement mechanism for affected individuals.

S. 2620 has recognized EPA enforcement inadequacies and provided pesticide producers the right to seek not only injunctive relief but damages and attorney's fees as well in cases involving data misuse by competitors.

Inclusion of a parallel private right of action for workers and the public to seek the protections they are afforded under the law is only equitable and just.

No. 2, no effective mechanism to remedy employer discrimination against employees.

S. 2620 has recognized the problem of discrimination against employees who exercise rights related to the pesticides act and included a prohibition against such discrimination. However, the bill provides no meaningful remedy to employees in the event of discrimination. EPA could fine an employer who violates the law, but there is no provision to allow reinstatement of fired employees or payment of back wages.

No. 3, no requirements to develop farmworker health and safety standards.

Under a 1975 court decision, primary Federal responsibility for farmworker and applicator protection from pesticide exposure was found to rest with EPA and not OSHA. But citing ambiguity in statutory authority, EPA has taken no action to promulgate worker health and safety standards on individual chemicals or generic medical surveillance, monitoring or training requirements.

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[1] See p. 126 for the prepared statement of Mr. Power.

To fill this void in farmworker protection, the AFL-CIO favors statutory language placing farmworkers and applicators under the Occupational Safety and Health Act which is directly geared toward worker protection. In the absence of such a transfer, however, Congress must direct EPA to finally develop and promulgate health and safety standards to protect farmworkers and applicators exposed to pesticides.

Four, provisions for the release of health and safety data are too vague.

As this committee is aware, section 10 of FIFRA which sets forth requirements for release of health and safety data to the public has been a controversial subject both in the current 1982 reauthorization as well as during deliberations on the 1978 act. Labor, environmental and farmworker groups believe the language of the 1978 statute is sufficient to protect against the release of trade secrets and misuse of data. Pesticide producers believe greater restrictions on data disclosure and use are needed.

The AFL-CIO has not opposed the section 10 language in H.R. 5203, although we do have serious concerns that the provisions, particularly those concerning innovative methodologies were adopted without any real congressional consideration. In addition we are concerned the adoption of new section 10 provisions that may be met with court challenges by individual pesticide producers, despite assurances of the pesticide producers trade association.

Unless the statement of principles regarding data disclosure is included in the statute itself, this is the point alluded to by my colleague, the AFL-CIO must vigorously oppose any section 10 changes under consideration. We urge this committee not only to adopt the statement of principles contained in the House bill, but also to provide a full hearing and consideration on the issue of innovative methodologies and the impact of data access and use restrictions on the scientific process.

Point 5. States are prevented from taking necessary actions to protect their citizens.

H.R. 5203 contains unfortunate language which sets up extreme barriers to States who wish to go beyond the Federal Government in requirements for data. Even greater restrictions on State activities are proposed by S. 2621. Federal EPA is given authority to determine what is a local concern and may disallow State requirements for data.

The provisions of S. 2621 and H.R. 5203 set up a bureaucratic system that will make it impossible for States to gain access to necessary data on which to base their decisions.

In summary, S. 2620 and S. 2621 are geared solely at serving the needs and interests of the pesticide producers. The problems of the public and workers related to the FIFRA have not been addressed by these bills, and indeed are severely aggravated by these legislative proposals. Amendments to assure worker protection, discrimination protections, a private right to seek enforcement through the courts and provisions setting forth principles for data disclosure are needed. Amendments restricting State activity must be deleted. In the absence of such amendments, the AFL-CIO must oppose S.

2620 and S. 2621 and seek to maintain the integrity of FIFRA through extension of the 1978 act.

Thank you for your time, Mr. Chairman.

The **Chairman**. Thank you, sir.

Ms. Warren, I was interested in your testimony. I am interested in everybody's testimony, but I think I ought to make a distinction that may not have been evident in your testimony. The agreement to which you referred was made by the House committee staff, not the staff of this Senate committee.

Ms. **Warren**. But to the extent that people supporting that are representing that there is some sort of agreement among the parties that this represents what we worked out, we do not feel that our part of the bargain is there anymore, so that agreement does not exist.

The **Chairman**. I understand. But the agreement was worked out on the other side.

Ms. **Warren**. Yes.

The **Chairman**. Thank you.

I have done the best I know how to understand the problem and to be a part of the solution. Let me check my information with you folks.

Am I correct in my impression that industry originally came to Congress seeking to limit access to the data only to summaries available in a reading room in Washington? I believe I am correct on that.

Since that time, industry, the environmentalists and other public interest groups, and the EPA have worked extensively to come up with an acceptable proposal. I know you are not satisfied with the product, but that is the background of the process. And that effort produced the amendment contained in S. 2620. And now, however, I am speaking to all of you, not just Ms. Warren, the testimony indicates that this provision is not acceptable.

Now, maybe I ought to ask what precisely would be an acceptable change to the provision to, one, do what you want and, two, offer some protection to the valuable data and technological information? What precisely could we do that we have not done?

Ms. **Warren**. Senator, the chronology that you gave really should go back a few more years because before 1978 there was no disclosure. The data were all withheld and we were the ones who came in 1977—1977 and 1978—and said that EPA has had one disclosure after another of unpeer reviewed data leading to problems. We want to be able to see these data.

We went through the same debates. The industry made the same statements about it and Congress hammered out what they thought was a compromise. Industry said they accepted that compromise but proceeded to file lawsuit upon lawsuit as soon as it was enacted so that it was never implemented. Then as soon as they lost all their suits and Congress right to legislate the disclosure of that data was affirmed, they came back and said, "Change the law." So we were starting from a position of saying, "We have never had what we thought we agreed to the last time." It made us somewhat reluctant to compromise. But we did sit down and talk about what kind of accommodation we could find. But innovative methodology is a very indeterminate body of information. They have never been able to explain to us exactly what is in it.

When industry is given the option to claim information confidential, whatever they feel ought to be confidential, they put confidentiality claims on everything. So, from our point of view, we are going to see innovative on everything also. And data which deal with finding pesticides in the environment, with environmental fate, which is the achilles heel of trying to do something about a large number of pesticides, is the very kind of information that will be called innovative methodology and which will not be peer reviewed, although citizens are going to be exposed to the substance in question.

What if Dow Chemical Co. comes and says, "This is a dioxin-free 245T," and we say, "How did you come to that conclusion"? "Well, that's a trade secret."

They have at least conceded that if we know enough about it to know that they have made the claim of innovative methodology we can ask the question, and we can see it but we cannot tell anybody very much about it. And the general scientific community is not going to know about that, nor will the applicability of that methodology to some other pesticide be available for 5 years.

It seems to me that it is a great intrusion on peer review.

I have a letter that I wanted to attach to my testimony, that I ask permission to put in the record, from 10 government and independent scientists from California.

The CHAIRMAN. Without objection.

[The following letter was received by the committee:]

JUNE 21, 1982.

U.S. CONGRESS,
Washington, D.C.

DEAR MEMBERS OF CONGRESS: We are gravely concerned that amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), now under consideration in the House of Representatives and the Senate, will have a long-standing adverse affect on scientific inquiry and reduce protection of human health and safety.

H.R. 5203, S. 2620 and S. 2621, the bills pending before both Houses of Congress, reverse the 1978 statutory decision of Congress regarding public and scientific review of the premarket test data conducted to determine whether pesticides endanger human health. Section 10 of FIFRA provides that such data—generated by the producers of pesticide products—shall be available for scrutiny by scientists and the public. The Act protects trade secrets and gives the Environmental Protection Agency (EPA) certain discretion in what it requires be disclosed. Yet without this peer review, as allowed under the 1978 Act, there is no way of knowing whether testing on these substances has been conducted thoroughly and the data honestly presented to the regulating agencies charged with protecting the public's safety.

That is the crucial issue, in our view. The public has a right to know what and how scientific studies are conducted on potentially hazardous substances to which the public is widely exposed. It is no secret that some premarket testing in recent years has been conducted under less-than-rigorous standards, resulting in charges that testing was incomplete, inadequate, or the conclusions fraudulently reached. Premarket test data—the most crucial measure of a substance's potential effects on humans and the environment—must be available to the public.

H.R. 5203, S. 2620 and S. 2621, however, would seriously hinder the ability of scientists and the public to review premarket test data. Section 5 of H.R. 5203 as reported from the House Committee on Agriculture would:

(1) allow access to the data "but impose conditions governing further copying or transfer of the data;"

(2) severely limit the public's access to scientific studies that utilize "innovative methods or technology," a vague term that the amendments define as "innovative methods or technology (including innovative methods of using known technology)

that are not otherwise publicly available, that are employed in obtaining product chemistry, residue chemistry, and metabolism data that are substantially different from known methods or technologies and innovative compositions of matter;" and (3) place constraints on how "scientists and [public interest or labor] representatives may communicate with each other and with the [EPA] Administrator, and in judicial or administrative proceedings concerning the innovative methods and technology without disclosing them to the public."

The "innovative methods and technology" restrictions are especially unacceptable because much scientific research could be classified as such.

The bills abrogate the essence of important safety precautions that were carefully drawn by Congress in the past with the aim of balancing protection of public health with reasonable regulatory measures designed to encourage the marketing of useful pesticide products.

We strongly urge members of Congress to consider the ramifications of not allowing premarket test data to be reviewed and critiqued fully and freely by both the scientific community and the public. We do not believe that such testing should be conducted behind closed doors or its findings kept secret. Scientists welcome the opportunity to share their findings. Peer review is accepted as a way of measuring the merits of scientific research and study.

We do not believe that public access to premarket test data, once it is completed, unfairly benefits competitors in the pesticide marketplace. Trade secrets can be protected without restricting scientific communication. There is no evidence that economic harm will accrue to the pesticide industry if safety testing data is made public. Patent laws and other provisions of law adequately defend industry investment in research and development of pesticide products.

It is these provisions of the bill with which we are concerned. We urge you to oppose all three FIFRA amendments as drawn and to support the existing provisions of the 1978 law that require premarket test data be readily available for public scrutiny.

Sincerely,

Dr. Marvin S. Legator; Dr. Miguel Altieri; Dr. Samuel Epstein; Dr. Frederick Plapp, Jr.; Dr. Kim Hooper; Dr. Guideon Letz; Dr. Jon Rosenberg; Dr. Julia Quint; Dr. Richard Jackson; Dr. Bob Stevens; Dr. John Harris; Dr. Norman Gravitz.

The CHAIRMAN. I understand precisely what you are saying. I have been in your fix myself many times in the Senate trying to get the precise meaning of a bill. I have often been reminded of Humpty Dumpty in "Through the Looking Glass," who said, "When I use a word * * * it means precisely what I choose it to mean, neither more nor less." However, the explanation still doesn't tell me anything. I understand what you are saying, but can you be a little more definitive about S. 2620, and tell me how it actually denies access to any data that is available from EPA currently?

Ms. WARREN. With respect to all data; or are you talking about innovative methodology?

The CHAIRMAN. Whatever.

Ms. WARREN. For innovative methodology, a member of the press, for example, would not be able to get the information. You have to be a State or Federal official, or a scientist working in the field, or a member of an environmental public health or labor organization, and you will get access but it is limited. You will not be able to discuss or publish about it. But you will have access to it. I would assume that a member of your staff would not be able to get it either unless there is some overriding congressional authority that allows you to get past these restrictions and get the data. And I think the only reason we were given access is because we were sitting around the table during the negotiations.

The CHAIRMAN. I guess what I am asking is what could a layman do with it anyhow?

Ms. **Warren**. The question is not so much of layman as the general scientific community finding out about developments which, because of the nature, bear on research that they may be doing, and that they could apply. I think that is the way the scientific process works, the give and take of seeing what someone claims to have done, trying it out, and finding out that this is not the case at all, or that this is something quite innovative and using it somewhere else.

The **Chairman**. Well, do not let this be mere colloquy between——

Ms. **Warren**. The competitor could not use it without paying for it. That is the point. There is a provision in there that requires competitors to pay for use of the data to register a pesticide.

The **Chairman**. What I am saying is I hope everybody will feel free to move in and comment.

Ms. **Seminario**. I would like to add a comment on that.

The innovative methodology section has concerned the AFL-CIO because it was adopted in the House bill virtually with no discussion. The innovative methodology language was not present in the earlier versions of the House bill, and was not the subject of hearings. No scientists came in and presented testimony on the issue on either side, the industry or ourselves. The chronology was such that the House language was basically agreed to—I should not say "agreed"—derived and proposed after lengthy hearings had been held in the House. It was a whole new issue. We have had some informal assurances from the industry that "innovative methodology" status will be claimed in a small percentage of data packages, and that within those data packages it will be a very small percentage of the data. But it is still very difficult to get a handle on exactly what is meant by "innovative methodology." In some cases all we have to go on is what has been claimed using restricted data, even though it may be trade secret data. We are not sure sitting here today what the industry means by that.

Another problem that we are concerned about with innovative methodology, is that the statutory language restricts the individuals that may have access to it. It then goes further to restrict what those individuals can do with data. The language allows some general discussion among scientists, but there is indeed a prohibition against scientists writing an article which would specifically speak to that "innovative" method and critique it in a serious and scientific way. Therefore, the evaluation of these methods, be they valid or not valid, is very limited and must be limited to generalizations. For instance, you could not have a conference on a number of different test methods that were trying to detect pesticides in the environment, and discuss "innovative methodologies" in the same way that you might discuss other methodologies. So it is not just the fact that these matters are restricted as to who can get access but what can be done with those methods is treated in a different way than other health and safety data. So it is for those reasons that we are concerned.

In summary, we do not know exactly what constitutes an innovated methology. Access to these methods is restricted to a few individuals and discussion and full evaluation of these methods is limited. We are concerned with that.

The **Chairman**. Maybe I could focus in on what I am trying to ascertain by asking my fellow North Carolinian, Dr. Guthrie, a question. Do you advocate dropping entirely the so-called innovative methods and technology provision?

Dr. **Guthrie**. That is what I would advocate. My problem is with the wording. I made the mistake of going to my dictionary. "Innovative" means to introduce as new, or as if new. How can scientists make decisions on health unless they have free access to all the information?

Now, I do not quite know what "innovative methodology" is. If innovative methodology is something like finding metabolites which the rest of the public does not know about, and it is said to be a very toxic metabolite, it would immediately change the whole criteria. In that, innovative technology is certainly not for the good of the public.

It seems to me that, as a scientist, I do not see how you can possibly act without all of the facts available. This seems to restrict that. For example, I read this proposed regulation and my colleague here reads it differently than I do. She said scientists acting as "independent scientists working in the field." She suggests that scientists could be working in the entire field of science. When I read that, I thought they meant scientists working in the field, one specifically covered by that particular part of science. I do not see who is covered and not covered in this bill. If I ever go in and start working on it, I might find myself in the middle of a lawsuit, and I would be very reluctant to do it.

The **Chairman**. Well, you see the fix I am in. Nobody can contest or challenge your suggestion that public interest ought to be protected. On the other hand, I find merit in the suggestion that there ought to be some sort of safeguard about competitors raiding something that you spent millions of dollars perfecting or developing. So that is what we are trying to do.

Ms. **Warren**. Senator——

The **Chairman**. Let me get through. If you will forbear for just a minute, I have to go down to the White House, and I am going to ask Senator Melcher, after one more question, if he would take the gavel and preside while I am gone. Senator Hayakawa will be here in a minute as well.

Let me go to Mr. Power, if I may. With regard to the authority of companies to enforce the data release provisions in this time of rather severe budgetary restraints, would you prefer to have the EPA spending its allotted funds for this purpose, or what? EPA, apparently, is not going to be able to do everything, you know. What would be the AFL-CIO's position?

Mr. **Power**. Mr. Chairman, let me defer to my colleague from our Office of Safety and Health.

Ms. **Seminario**. The AFL-CIO has not opposed the private right of action that has been written into both the House version and the Senate version for pesticide producers. We do have concerns similar to those Ms. Warren raised, the language on commercial use being restricted so that an independent scientist uses the data and then may be sued for it. That seems to be a punitive provision. But in that same vein, I recognize that companies may have some problems with EPA's ability to enforce their rights under the law. We feel that EPA has a similar problem presently in its ability to enforce worker rights under the act.

What we have suggested, in the spirit of justice and equity, is that workers and the public be afforded essentially a parallel right to seek some kind of redress and relief from pesticide exposure through the Federal courts.

The CHAIRMAN. The sound was a little muffled. I think I understood what you said.

Now, precisely what other authority under other laws or regulations, Federal or State, is there for actions by employees or other persons harmed by the misuse of pesticides?

Ms. SEMINARIO. I think what was being referred to before was that under State law employees or other individuals may have some rights. I am not a lawyer and I am not fully versed in what those laws might be.

The CHAIRMAN. Let me confer with staff. Are there other authorities? Identify yourself and answer the question.

Mr. CLARK. Tom Clark, deputy counsel to the committee.

Mr. Chairman, it is our understanding that there have been a number of lawsuits under State authority. That is, State laws in different States provide some basis for protection to people that are harmed by the misuse of pesticides. I believe there are also personal injury types of lawsuits that are generally filed in the State courts or in the Federal court if there is diversity of citizenship, which have been used in the past to seek some redress against a company. On the other side of the issue, if you set up a mechanism for companies' data to be restricted in redistribution, once it has been distributed to the initial requester, the number of instances where the data may then be further released could be substantial. Just tracking down alleged violations and checking them out could be quite a burden on EPA. We see a very big distinction—the staff does, and I think so do a lot of other people working on it—see a big distinction between a private right of action, where there is already a body of law and some authority, and the situation where we create protection against a redistribution with penalties for violations, and then want to impose this new enforcement responsibility on EPA. They do not have the funds to go out and track down violations.

The CHAIRMAN. That was the point I was making, just how EPA funds are going to be used.

John, I am going to ask you to take over.

[Senator Melcher assumed the Chair.]

Senator MELCHER. Thank you, Mr. Chairman.

Did I understand your response correctly that you saw it as a right of action for an individual against whom, EPA or the manufacturer of the drug?

Ms. SEMINARIO. Specifically seeking it against the applicator.

Senator MELCHER. Does not that right now exist?

Mr. CLARK. The right to?

Senator MELCHER. Of an individual who is injured. Does he not have a right to sue the manufacturer or the applicator?

Mr. CLARK. Yes, sir, but it would not necessarily be a right under this particular law. It would be a right under general State law.

Senator MELCHER. Why do you say "under general State law"?

Mr. **Clark**. Generally State laws provide that if a person is injured by another person, he can sue. It is a tort action.

Senator **Melcher**. A tort action.

Ms. **Seminario**. There is a difference between seeking damages after an individual has been sprayed or damaged in some way and seeking some redress, or some compensation and being able to seek an injunction to stop an applicator from spraying insecticides. I am not that well versed in State law, but I do not know that any State law allows at present for somebody to go into court and, basically, take a legal action to have an applicator suspend his activities in that area. I just really do not know. Rather than get into any further discussion myself, we will be glad to research that and send in writing an opinion to put in the record.

Senator **Melcher**. Dealing with an individual who was injured?

Ms. **Seminario**. That is correct.

Senator **Melcher**. Ms. Warren, are you advocating that a State have the right to deny use of a chemical until it is approved by the State?

Ms. **Warren**. Oh, definitely. I think, as a minimum, a State ought to be able to say it cannot be used until it has been approved by them. I do not think S. 2621 would change that. I think it makes a distinction between where the questions have to do with health and safety or whether they do not, and it says a State must register the pesticide—unless it concerns an issue dealing with health or environmental effects in areas of special local concern.

The concern that I have is that EPA does not have a very good record in the area of pesticides regulation. They inherited a lot of problems from the Department of Agriculture in 1970 and the 1972 amendments put them into a process of trying to evaluate all of those back studies. One of the major testing laboratories that did a lot of the studies that underlie pesticide registrations was found to have routinely falsified the data and their officials have been indicted because of that, but there is a very large number of studies that were done by that laboratory which raise serious questions about whether those pesticides have a valid basis for being registered in the first place. And, then again, EPA does not ask all of the right questions. They do not ask about the example I gave before, whether the pesticide is likely to contaminate drinking water and ground water. And that has been a problem and States should certainly be allowed to find that out before they permit the pesticide to be used there.

Senator **Melcher**. Drinking water?

Ms. **Warren**. Yes, California and New York have had serious ground water, well water contamination problems from the use of pesticides, both from pesticides which were registered by the EPA—one of them was from the burial of pesticides and the other was from the use of it on potatoes. EPA apparently just did not ask the question about how this pesticide behaved in sandy soil. And it has contaminated many, many wells on the eastern end of Long Island, a problem that should have been anticipated and asked about and looked into before. It seems to me that that is the kind of problem that a State is likely to have and they should be able to ask that question, but not just assume the pesticide is safe because it is registered by EPA, when the history of EPA's pesticide regulatory process does not warrant that assumption.

Senator **MELCHER**. Then your point is not that you find a citizen of a State wanting to use a pesticide and the State has not chosen to even look at it? You are not suggesting that I should not be able to use it?

Ms. **WARREN**. That you should not be able to use it—it has to be registered in the State. I think the way the programs work, every pesticide has to be registered in the State before it can be used there.

Senator **MELCHER**. What if the State never acts?

Ms. **WARREN**. If the State never acts?

Senator **MELCHER**. Yes.

Ms. **WARREN**. I think that probably needs an answer from EPA.

Senator **MELCHER**. What happens if a State never acts on a pesticide?

Mr. **CLARK**. Senator, your question is if a State does not act?

Senator **MELCHER**. Does not act affirmatively to approve a pesticide.

Mr. **CLARK**. If the State has a law that requires registration in the State, it could not be marketed in that State. The Federal registration is EPA's registration and can be overridden by any State. The only thing a State cannot do, Senator, is to approve for sale in the State a pesticide that has been disapproved at the Federal level.

Senator **MELCHER**. But for the occasional use of pesticides for a dog, does the Federal law require that the State approve it? Or are you telling me that all States have a similar law that you just described?

Mr. **CLARK**. Senator Melcher, it is my understanding the Federal law does not require that the State approve a pesticide for use. My understanding is, I believe all States do have some form of registration of pesticides. A company that wants to sell a pesticide in the States would have to comply with varying degrees of registration.

Senator, one other possibility, the Agency's representatives are here and, if you like, I am sure they will comment on this further.

Senator **MELCHER**. Is that uniform?

EPA **STAFF**. Senator, the Federal statute does not require States to run their own registration programs but under present law it allows them to. And most of them do, in fact, have their own registration program, which vary from State to State.

Senator **MELCHER**. You are not asking that if a State has not chosen to require every pesticide to be registered no matter how limited its use, that they be required to do so?

Ms. **WARREN**. No; we just would like the States to do what they feel they need to do with respect to registering pesticides for use within their own borders.

Senator **MELCHER**. You find fault with what section here?

Ms. **WARREN**. It is S. 2621, which I think is the other shorter bill. That one requires the State to effectively ask EPA's permission to approve a request for more data than EPA asked for itself.

Senator **MELCHER**. What are you referring to?

Ms. **WARREN**. The current law allows the States to do that. The States can pretty much do what they want to under section 24(a).

The State of California is probably the largest user of pesticides in the country.

Senator **Melcher**. I am trying to pin down specifically what you object to, 24(a)?

Ms. **Warren**. 24(a), as it presently exists, is one sentence which says States may regulate the use and sale of any Federal-registered pesticide or device in the State, but only if it has not been prohibited by FIFRA. And the bill is a great enlargement of section 24(a) that would require EPA to approve the State's additional data request. It makes the State go through a lot of procedural hoops, and if the Administrator agrees with it the State can be sued about it. It just creates a lot of deterrents for the States seeking to request any further information. It is very cumbersome procedurally and subjects the States to liability for suits over data requests before they can be made.

Senator **Melcher**. What you are referring to is (a)2?

Ms. **Warren**. There are several different provisions that distinguish between information on pesticides for special local needs or information where there is not a special local need, but the State just wants additional information about the pesticide. The Administrator can be asked, do they really need it, and is their request reasonable. And if EPA feels that it is, the State can make the request. If EPA does not think so, they can overrule the States.

It makes the EPA a policeman over the State's individual registration provisions.

Senator **Melcher**. We should just leave the present alone; is that what you are testifying?

Ms. **Warren**. Yes; I would like to see some evidence of great abuse by the States before the law is changed to impose on States the kind of procedural requirements that that bill would do. And I do not think a case has been made. It also puts a great new burden on EPA to intrude itself into the States' registration process. EPA is not in favor of it either.

Senator **Melcher**. Is Mr. Early still here? Dr. Early.

Dr. **Early**. Yes.

Senator **Melcher**. Mr. Early, is there any evidence, you represent the whole association—is there any evidence that the States are more amenable to producers or manufacturers, whatever you want to call them, members of your association?

Dr. **Early**. More amenable, by that do you mean they are more likely to register products easily or something like that?

Senator **Melcher**. Yes; if I am a manufacturer in California, am I more likely to get along with the State better than if I were a manufacturer in New Jersey?

Dr. **Early**. I think we would have to look at the individual States.

Senator **Melcher**. I am asking about California.

Dr. **Early**. California has represented a difficulty for us, Senator, for the last several years, primarily because we were concerned that the registration process in California was moving so slowly that they would have, in some cases, maybe a year or so before the Agency acted on a request for registration after the Federal Government had already accepted the product and registered it federally. That has been a major concern of ours. The other concern is we do not really think it is necessary, to paraphrase, to rediscover the wheel, once you have gone through the process at the Federal level.

We do recognize, and we have always said this, that the State has the right, and they should have the right, to ask for information that they feel meets the special local need situation.

May I give you an example?

Suppose one of my companies were to register an insecticide for use on citrus fruits in Florida, and we find that in Florida we have a rather different environmental situation than you do in the desert valleys of California. A residue situation may develop in California that could be significantly different than what you have in the State of Florida, where they have a great deal of rainfall. So, in that situation, I think it is appropriate for California to say, "Hey, we have a unique situation. We get no rainfall and we are going to have a residue situation in California." That is the kind of special local need information they should be able to legitimately ask for, and they do ask for that information.

Senator **MELCHER**. Is there any evidence that if you are a manufacturer in California it is easier to get State clearance?

Dr. **EARLY**. Easier to get State clearance of other States?

Senator **MELCHER**. No, from California. Is there any parochialism?

Dr. **EARLY**. I do not know that there is, no. I am not aware of it. I hope there is not.

Senator **MELCHER**. I assume you have a lot of members from California.

Dr. **EARLY**. From California and all over the country, yes, sir.

Senator **MELCHER**. What about some small outfits; do you represent them, too?

Dr. **EARLY**. We have some small members also, yes.

Senator **MELCHER**. What do you call small ones? What size operation?

Dr. **EARLY**. I do not want to put a value on it, but from a personnel size, I would say you have an operation that maybe has a formulating plant with, say, less than 10 to 15 employees involved in the process. Essentially, there is no research and no innovative work.

Senator **MELCHER**. And that is all of the employees or just one little branch?

Dr. **EARLY**. If I owned a small plant and my wife was the secretary, that sort of thing. I am not talking about a subsidiary of a large corporation.

Senator **MELCHER**. No, we are talking about Mom and Pop outfits.

Dr. **EARLY**. Yes, we have some of those. You would probably find a little better representation from another organization, the Pesticide Producers Association.

Senator **MELCHER**. They might have more of the smaller ones. Is there—let us see, who testified there?

Dr. **EARLY**. John Wise.

Senator **MELCHER**. John Wise.

Mr. **WISE**. Let us not talk about my company.

Senator MELCHER. We are talking about your membership. How many are in your association?

Mr. WISE. We have about 50 members nationwide.

Senator MELCHER. Is it all for plants?

Mr. WISE. For plants? Do you mean formulation companies?

Senator MELCHER. No. You say pesticide producers, is this all for use on plant life?

Mr. WISE. Most of it is. We may have some companies that are involved in home type aerosol products, et cetera. But, primarily, most of our members are in the agricultural field.

Senator MELCHER. Mr. Early, do you represent companies that produce chemicals that are not used on plant life, but for use on animal life?

Mr. WISE. Oh, yes, the whole broad spectrum of pesticides includes pesticides, fungicides, rodenticides, animal and plant.

Senator MELCHER. Yes, I know that. The act covers that and I assume most of your associations would.

Dr. EARLY. I am sure John has some members that sell insecticides for cattle.

Mr. WISE. Usually, with agricultural insecticides, we are talking about products used in the production of agriculture, not only animal but plant life also. Some products are used directly on animals, parasite control.

Senator MELCHER. What are they using on those ticks? What are they using on those cattle ticks that are coming in from Mexico?

Mr. WISE. Most of those right now are being dipped, I think.

Senator MELCHER. With what?

Mr. WISE. Those coming in, the primary product I think that is being used is probably Toxophene.

Senator MELCHER. Would you have Toxophene manufacturers?

Mr. WISE. We have Toxophene formulators.

Senator MELCHER. Mr. Early, you would have Toxophene manufacturers?

Dr. EARLY. Manufacturers.

Senator MELCHER. How tough is it for getting something used on animals, for instance rabbits, for ticks or something in their ears? How tough is it to get it approved?

Dr. EARLY. I have not had any personal experience with that sort of registration process. I would think if it is involved in an animal that could be used for food products, obviously, you are going to have to go through a process. If the product is used, it may have a residue when the product can be consumed, but without injury to the public. But I am really not an expert to give you the exact procedure that one should go through. I am sure that people from EPA can respond to that in detail.

Senator MELCHER. How tough is it to get a pesticide that is not going to be used but in a very small market to get it approved?

Dr. TODHUNTER. That depends on who you ask. From State to State it varies quite a bit. The problem we have is we do not get very many requests for registration of the so-called minor uses. This has been a continuing problem in the whole area. We generally find the registration for minor use no more difficult at the Federal level than, say, the one for a larger, broader use. Very often the reason in the minor use is an extension of some existing product. We are fairly familiar with it.

Dr. GUTHRIE. In the State of North Carolina about 20 of those are approved every year for minor use.

Senator MELCHER. For minor use?

Dr. GUTHRIE. Yes.

Senator MELCHER. And they have already been approved by EPA?

Dr. GUTHRIE. They would not have been, no.

Senator MELCHER. Is there an exemption?

Dr. GUTHRIE. They might have been approved by EPA for some other use, but that particular minor use was not approved.

Dr. TODHUNTER. I believe Dr. Guthrie may be referring to a section 24(c), special need registration. But, even so, we normally would not allow the use of a material that was not registered for some other use.

Dr. EARLY. Sir, if you would like to pursue the rabbit issue, Ralph Engel is here who can really give you better information than I can. He represents another spectrum of the industry. There are too many of us around, I quess, but he could address that issue. He is in the home and garden area which is more specifically involved, if we could get him to volunteer to respond.

Senator MELCHER. Do you volunteer?

Dr. EARLY. He appears to be anxious to come up and respond.

Mr. ENGEL. Senator, I think your remarks have been directed to 24(a) of FIFRA with regard to the registration of pesticides in the State. More particularly, I think you are addressing the nonagricultural uses of pesticides, if I am understanding.

Senator MELCHER. I don't know what you mean by "nonagricultural."

Mr. ENGEL. Not used on a farm product.

Senator MELCHER. But used on an animal?

Mr. ENGEL. Used on an animal or whatever, like a flea and tick spray and you have to get a registration.

Senator MELCHER. How tough is it?

Mr. ENGEL. We know that because we have surveyed every one of our members. They first tell you it is running between 15 and 18 months to get it looked at in that State before you get a response. Understand also that the seasons are roughly set up and because of climate conditions you pass one or two seasons before you even get looked at in that State.

Senator MELCHER. Then it is tough.

Mr. ENGEL. Indeed, it is. One more point I would like to make: S. 2621 does not preempt or take States rights away. It permits the States to regulate the sale and use of a pesticide, just as it does today, what it does do is eventually to register the pesticide within a given period of time that is reasonable and, two, we would like you to collect data that is relevant to your issue. There is no one in our industry that wants to deny States the data that is relevant to their local concerns. The only thing that we want to stop is the collection of data that is irrelevant and, in California, to collect it on every single registration that is submitted to the State whether it pertains to the product or not.

Senator MELCHER. Well, California happens to be a huge agricultural producer of so many diverse crops that perhaps they just have more problems. And if they use something that should be used rather heavily, perhaps it is because of the nature of the State.

Mr. ENGEL. We understand that, Senator. When you dig into this issue you find, basically, there are major delays because of lack of funds and personnel in the State to reproduce an EPA within the State as it exists in the Federal Government. And that is exactly what the State of California is attempting to do. And they cannot duplicate what over a thousand scientists at EPA can do. They do not have the funds to do that, obviously.

Basically, Senator, there is a problem of logistics that cannot be resolved, and that is every pesticide registration is not a problem. A Pyrethrum pesticide has been in existence for 50 years, and when you treat it the same way as another pesticide that may be a problem, you are going to tie up every facility in the State and get nothing done so no registrations or consequences are occurring in that State.

Senator MELCHER. Well, how would, if what you are thinking then is that S. 2621 will force the State of California to get more personnel?

Mr. ENGEL. No.

Senator MELCHER. If they do not have the scientists, how are they going to provide the extra data that would be required under S. 2621?

Mr. ENGEL. I think S. 2621, or 24(a) amendment, as it is laid out, is a simple mechanism to set up two piles, if you will. And if we can use my hand for example as the lever, you are going to have one pile about this high that may be or may not be a problem. But the State can say, "We believe there may be a special local concern here, and we have the right to collect data." There is going to be another mountain that has no problems and should be zipped right through.

Senator MELCHER. All right, sir. And you want to separate those out?

Mr. ENGEL. I think we want to set up a mechanism within the State that says, "Let's be fair about this." And it does two things, basically. Senator Hayakawa's bill does two things. It says you have a right to collect data, but it should be relevant to the pesticide use and the pesticide you have at hand. And the second thing it would do, if you want to register a product, you should register it within a reasonable period of time.

It does not deny the State some banning of pesticides. In fact, a State under that bill can deny the registration right up front, and no action can be taken to stop it.

Senator MELCHER. Do you have a quarrel with that?

Ms. WARREN. Senator, I think if they have a problem with the way the State of California is doing it they should go back to California and straighten it out there.

Senator MELCHER. That is what they are suggesting.

Ms. WARREN. No; they are not. They are saying the EPA should decide what is relevant for California to have rather than letting California decide. It is not a problem in every State. It seems to me you do not have to amend the Federal law to take care of what they perceive to be a problem in California, though there is disagreement whether it really is a problem. Of course, the people from California will be in tomorrow and I think the question should certainly be put to them at the same time.

California knows they have limited resources. To some extent, it does not seem totally believable to think they are just going to go off on tangents on every pesticide and ask for a lot of information they have no reason to want.

Senator **MELCHER**. I read this to say a State may require submission of additional data, provided that the State shall give the applicant written notice at the time of the request for purposes of justification.

Ms. **WARREN**. And beyond that, provided that if there is disagreement the EPA Administrator is asked whether the information is relevant or necessary, and must make the determination of whether the State's request is arbitrary and capricious. It does put EPA right into the middle of it.

SENATE STAFF. Senator Melcher, if we could try to clarify it just a little bit. EPA's role under S. 2621 would be as a judge, and the standard that they would judge would be whether the request is arbitrary and capricious. So that is a little different than saying they are going to judge whether or not the States, what information the States can request.

The States can request any information so long as they give a reason for it if it relates to a special local concern.

Senator **MELCHER**. The statement has been made that a State could just reject——

SENATE STAFF. That is correct. If the applicant refuses to produce the information, a State can deny the application. That is the most direct way to handle the problem. If a State makes the request and the applicant challenges the request by going to EPA, EPA would judge whether it was arbitrary and capricious.

Senator **MELCHER**. On the final analysis, could the State deny it anyway?

SENATE STAFF. If the Administrator determined that the request was arbitrary and capricious, then the State could not deny the registration for not producing that data. So, in that instance, no, the State could not deny it for that reason. I do not think that would prevent them from denying it for another legitimate reason if there was a reason that existed.

We are talking about special local concern; that is information related to special local concern.

Senator **MELCHER**. In the final analysis, the State determines that it would be harmful in their case, can they deny it?

SENATE STAFF. Senator Melcher, the State can deny the registration if the State determines it is harmful.

Senator **MELCHER**. Well, I am talking about for some other reason, because that is pretty broad. That is a decision of the State then?

SENATE STAFF. Yes, depending on State law. I understand that in California they seek data on efficacy. I understand that the State of California can deny an application if it was not established that the product does what it is held out to do.

Senator MELCHER. Is that a determination by a court? I am asking EPA.

Dr. TODHUNTER. No; it is determined by California State officials.

Senator MELCHER. So, in the final analysis, you think they could deny it? That this does not change it?

Dr. TODHUNTER. Well, it restricts their ability to communicate freely with the regulated community, and it interjects us into that State-industry dialog.

Senator MELCHER. That is not my question though.

My question is: Despite what is in this bill S. 2621, which I understand you oppose, if the State of California particularly decides on the basis of efficacy, whatever they choose to interpret that, how is it determined, it just does not fit, does not fit the needs of the State?

Dr. TODHUNTER. If the States were to decide on the basis of efficacy or any other reason to deny the registration.

Senator MELCHER. Does that not provide what you advocate?

Ms. WARREN. Senator Melcher, this bill would say what a special local concern could be, so it limits the State's definition of what its own special local concerns are. It says the State has to have significant factual information.

Senator MELCHER. Well, if this statement is true, that even though they oppose S. 2621, EPA opposes it, the State still has the option for whatever reason to deny it.

Ms. WARREN. Well, they can prohibit, but that still leaves them in a position of having to say you cannot use it at all. I think, ideally, they would like to be able to allow it to be used but want to ask a few more questions than maybe EPA asked.

Mr. ENGEL. Senator, the industry does not want an interminable length of time without knowing anything. You can sit for 2 years and not know what a State is going to do. If they are going to deny it, just give us a reason and get on with it. If they are not going to deny it, let us do something about it. That is it in a nutshell.

Senator MELCHER. I have no further questions. We will wait for that information on the rights you think the individual worker ought to be entitled to.

Mr. POWER. We will provide that for you, Senator.

Senator MELCHER. I understood Senator Hayakawa was coming here. He is not.

Thank you all very much. The committee is adjourned.

[Whereupon, at 4:15 p.m., the committee recessed, to reconvene at 10 a.m., Tuesday, June 22, 1982, in room 324, Russell Senate Office Building.]

REAUTHORIZATION OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

TUESDAY, JUNE 22, 1982

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, D.C.

The committee met, pursuant to notice, at 10 a.m., in room 324, Russell Senate Office Building, Hon. S. I. Hayakawa presiding.

Present: Senators Hayakawa and Boschwitz.

STATEMENT OF HON. S. I. HAYAKAWA, A U.S. SENATOR FROM CALIFORNIA

Senator HAYAKAWA. This morning, ladies and gentlemen, we begin the second day of hearings on proposed amendments to the Federal Insecticide, Fungicide, and Rodenticide Act of 1972. Currently, the committee has before it three bills, S. 2245, S. 2620, and S. 2621, which would amend FIFRA. This is our affectionate abbreviation for the Federal Insecticide, Fungicide, and Rodenticide Act.

The focus of this morning's hearing will be on section 24 of FIFRA relating to the authorities of States within the framework of our Nation's pesticide laws. As you are probably aware, the bill I have introduced, S. 2621, is limited primarily to section 24. While in my opinion changes are most definitely needed in this section, I am looking forward to the testimony this morning. The comments and suggestions of our witnesses will be given every consideration as we attempt to modify and perfect the legislation before us.

The House of Representatives' Agriculture Committee has held extensive hearings on all aspects of FIFRA. One thing we have learned is that section 24 is a very controversial area in which to propose a change. I am sure this morning's testimony will bear this out.

At this point, I would like to submit for the hearing record a copy of my floor statement which accompanied the introduction of S. 2621. The statement details some of my concerns and generally addresses the question of why changes in section 24 are needed. Also, I would like to include in the record a summary of S. 2621 prepared by staff.[1]

Both of these items are available on the press table.

Let us proceed with our first witness, Richard Rominger is the director of the California Department of Food and Agriculture. He is representing the State of California.

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[1] See p. 83 for a reprint of Senator Hayakawa's floor statement, see also p. 85 for the staff summary of S. 2621.

It is a real pleasure to welcome you here, Mr. Rominger. I thank you for coming. I know that you have a somewhat lengthy statement. At 11 o'clock, there is a meeting limited to Senators at which we will meet with Prime Minister Begin of Israel. We want to get through because I want to be there. Let us do this as quickly as possible, including what I have to say.

STATEMENT OF RICHARD ROMINGER, DIRECTOR, FOOD AND AGRICULTURE DEPARTMENT, STATE OF CALIFORNIA; ACCOMPANIED BY SUE MARKLAND MORELAND, ASSISTANT DIRECTOR, WASHINGTON OFFICE, STATE OF CALIFORNIA

Mr. ROMINGER. The proposed amendments to section 24(a) of the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA] deeply concern those of us in California who are attempting to administer a responsible program of pesticide use. It is our analysis and the analysis of other State departments of agriculture involved in pesticide regulation that the proposed amendments to 24(a) are in direct conflict with States rights and our shared objective to use pesticides safely.

As currently written, the section 24(a) proposals would remove authority from individual States to establish health, safety, and environmental measures in accordance with conditions occurring within States. In California, they would sharply diminish and nearly eliminate the capacity to protect workers and the public from potential adverse effects due to pesticide exposure. It would be equally difficult to continue protective environmental efforts that have, in recent years, minimized contamination problems due to pesticides.

In legislative history preceding enactment of FIFRA it was clearly recognized that health, safety, and environmental measures pertaining to pesticides should be tailored and carried out in accordance with needs of the individual States, and that issues of concern to the States should be addressed at the State level, with Federal involvement. In addition to FIFRA making such provisions in 1972, through section 24, similar authority allowing States to address issues of concern to the States is found in the Clean Air Act, Occupational Safety and Health Act, and Mining Control and Reclamation Act as well as the Natural Gas Pipeline Act.

I am here today to reaffirm California's opposition to any changes in section 24(a) of FIFRA.

However, there is one section in S. 2621 that we would support; that is section 1a(1), which states in part that "A State, but not a political subdivision of a State, may regulate the sale or use of any federally registered pesticide or device in the State * * *."

We need to maintain a responsive State regulatory program which adequately protects citizens of the State while allowing pesticides to be used to control pests efficiently and safely.

Testimony presented by California representatives over a period of more than a year has never whitewashed the fact that we have had problems in implementing the pesticide registration regulations that went into effect on January 4, 1980. The program was perceived by the uninformed as an impossible bureaucratic task. We recognized the program as a needed and important one that would require a 2-year implementation period. This implementation period involved an array of difficult and complex issues that have taken us the full 2 years to resolve. However, we are confident that the major issues surrounding delays in registration have been resolved.

California regulations have been changed in several ways just recently to provide relief to companies by: One, providing CDFA authority to waive or request summaries of all the federally required data, and two, conditional registration authority has been amended to provide more flexibility to register pesticides pending development of data.

The registration unit is now fully staffed, and training of all personnel has been completed. When the registration unit became fully staffed, we initiated an accelerated work effort in which the objective was to consider every application for registration in the department's possession in terms of the regulation changes and the other policies implemented to minimize delays. This effort has resulted in removing all but 125 applications from the system and an assurance by us that 2-year phasein commitment has been successfully completed. The 125 applications remaining in the system involve those in which extensions have been granted to registrants to submit required data.

All applications accepted by the registration unit will be acted upon within the timeframes specified in California regulations. These timeframes provide 60 days for products involving active ingredients presently registered and 120 days for new active ingredients and major new uses.

Although the Environmental Protective Agency [EPA] requires toxicology data in support of pesticide registration, data needed to make risk assessments is only required after products have been registered when adverse effects are suspected or have been identified. It has been unique for California to require the kind of data upon which risk assessments can be made prior to registration. This includes mixer, loader, applicator exposure data, indoor exposure data, skin absorption data, and data to support medical management to assist physicians in treating pesticide exposures. Unless these types of data are provided, accurate hazard identification and appropriate workplace and public health risk assessments cannot be made. California citizens would, therefore, be denied their rights under the proposed amendments and would find such an intrusion on States rights dangerous to public health.

In recent years, as a result of our ability to separately review toxicology data developed by registrants and to require additional data when necessary, California took action to eliminate most uses of DDT and DDD. California cancelled most uses of pesticides containing mercury, cadmium, and arsenic due to human health hazards. Rodenticides containing phosphorous were eliminated because of serious poisoning potential for children and the availability of safer alternatives.

On one occasion, California accepted a Federal residue tolerance for Guthion on alfalfa. This acceptance resulted in thousands of acres of hay with residues exceeding the Federal tolerance. Neither EPA nor the registrant could explain why excessive residues occurred. If residue data had been developed in California or under similar environmental conditions, the residue problem would no doubt have been identified.

California also accepted a federally approved residue tolerance for Di-Syston on alfalfa; subsequently cows became sick and died after eating alfalfa that had been treated. By examining additional data requested from the registrant, we determined that toxicity hazards of the breakdown products had been completely overlooked at the time of Federal registration.

EPA accepted data on the organophosophorus pesticide, Torak, for use on grapes. After 113 workers became ill working in a Torak treated vineyard, California raised questions about the presence of a highly toxic oxone analog in the formulated product. The product was voluntarily removed from the California marketplace by the registrant.

In the case of DBCP, California detected human infertility problems, as well as ground water contamination problems that led to cancellation 2 years before EPA acted. This year we cancelled structural uses of EDB because of the hazards posed by that use and because safer alternatives exist.

Since 1950, California has experienced a series of worker reentry poisonings in fields and orchards treated with organophosophorous pesticides. By having access to appropriate toxicology data, California has adopted worker reentry intervals for the most highly toxic pesticides which have prevented many more worker poisonings. These intervals were established on the basis of data we obtained but which was not required by EPA for registration.

California has been in the forefront of pesticide regulations. The California pesticide program was established in 1921. It was not until 1947 that the Federal Government established a registration program. California's program provided the pattern for establishment of pesticide registration and related activities under USDA and eventually EPA. These Federal programs consider pesticide use on a national scale and have been of a more general nature. Many of the Federal processes were established on the basis of measures initiated in California.

This has not been a partisan issue in California. The California Environmental Quality Act was passed in 1969, signed by Governor Reagan, and the Republican attorney general ruled that CEQA applied to pesticides, meaning that an environmental impact report is required for each application and it has resulted in the legislature directing the Drug and Food Administration to develop a program equivalent to CEQA.

In 1972, still during the Reagan term, the California Legislature, recognizing health and safety problems associated with the use of pesticides, directed the department of food and agriculture to develop a worker health and safety program and worker safety enforcement program. These programs are unique within the United States.

EPA, through its label improvement program, is presently considering proposals for pesticide label improvements which will include up-to-date, understandable safety procedures and precautionary statements that California's work health and safety program has urged for years, and California has been unable to change due to the Federal preemption statutes. We have recommended on numerous occasions that statement allowing self-administration of atropine tablets be removed from labels, since atropine used by applicators in this manner can mask symptoms of organophosphate poisoning rather than stop or reverse the effects of exposure.

We are also encouraged that EPA is now considering closed system requirements for category I liquid pesticides and has, in recent months, been working with our department staff on the technical aspects of closed systems. We are further encouraged that EPA is interested in worker reentry standards and is currently consulting with our worker health and safety unit on establishment of Federal requirements to provide reentry protection similar to that required in California.

The statements presented by you, Senator Hayakawa, on June 20, 1982, when you introduced S. 2621, are similar to statements supporting other FIFRA proposals and we believe substantial clarification regarding many of these statements is necessary.

It should be noted that California does not require health and safety data in addition to that required by EPA for 85 percent of the registration applications received. Current figures indicate additional data requests dealing primarily with health risk assessment are required for only 10 percent of the applications. Stated also is that such California data requirements do exceed those of EPA; while some California data requirements do exceed those of EPA in the areas of human health and risk assessment, EPA is currently considering registration and regulatory requirements similar to California to protect mixers, loaders, and applicators.

The 85 percent figure includes those products where we ask for efficacy data.

The point is also made that California and six other States have expanded pesticide programs to exceed or duplicate the Federal registration requirements. We believe this is an indication EPA has not been able to address the needs of the States.

Expressed also is the belief that S. 2621 would insure a proper balance between the role of the States and EPA. We do not see such a balance; provisions of the bill would make it very difficult if not impossible to obtain any human health data, especially that pertaining to mixers, loaders, applicators, or other workers before expiration of the 60- and 120-day period required for registration actions.

While it is true that registration could be denied if the necessary data were not provided, States would not, in most cases, know whether denial of registration would be necessary since it will not have the opportunity to consider the data.

Included also is the assertion that S. 2621 leaves intact State authority to regulate sale and use of pesticides. We disagree with this statement because it is obvious the bill would force States into registering products without the data necessary to evaluate applications before the end of the time allotted for registration decisions.

In response to the statement that California data requirements place a hardship on industry, it should be noted that registration requirements now in effect, while recognizing agricultural and health needs, protect pesticide registrants from marketplace intrusion by those interested in obtaining sales profits without having to meet registration requirements. For example, if a registration applicant does not have sufficient data to meet California requirements, such an applicant may obtain registration consideration only after having reached agreement with an appropriate registrant who has the data needed or who is willing to agree to registration of a label similar to that held by the primary registrant. In this, respect, the old "Me-too" concept where a number of registration applicants could obtain registration based on data not in their possession is eliminated. The marketplace is, therefore, protected from those registrants possessing the required registration data. At the same time there is an obvious reduction in liability to registrants based on the extensive public health and safety consideration made in the review of data required to confirm safe and effective use under California conditions.

Our current regulations also apply to registrants of disinfectants, sanitizers, and specialty products by way of enabling subregistrations and identical-product registrations where those wishing to market pesticides in accordance with labels already registered may, after receiving approval from the primary registrant and EPA, obtain California registration without submission of additional support data.

Consistent with flexibility of our current registration process, regulations which became effective on April 10 of this year provide a conditional registration procedure similar to that of EPA. On a case-by-case basis this will allow the Department to accept applications to register federally approved labels without requiring a summary of all the items submitted in support of Federal registration. In the case of new active ingredients, however, acute and chronic effects data along with preliminary efficacy data would have to be provided. Where the active ingredient is currently registered, only preliminary efficacy data and acute effects data will be needed.

We are enthusiastic about these new provisions and believe it will soon be possible to register many disinfectants, sanitizers, specialty products and agricultural formulations that previously could not be registered simply because EPA had not required all data listed in their registration guidelines at the time conditional registration was granted.

The statement that consumers and agriculturalists are deprived of needed products is also inappropriate. We have found, however, in some instances that it was necessary to restrict or even eliminate use of needed products such as in the case of the nematocide DBCP where continued use would have resulted in the contamination of ground water. In cases such as this, it has been traditional for the department to work with researchers, registrants, and the legislature to enable development of effective alternative materials and methods.

The comment implying there is a California policy for labeling fresh and processed commodities to inform consumers of the presence of various toxins, including carcinogens, is not true. Such a proposal was once made by a person not in the Department of Food and Agriculture, but was never discussed further and never implemented.

It was also suggested that California's program hinders registrants from making pesticides available for specialty crops because registrants cannot justify the expense of resources required to meet

California data requirements. This is not true. The problem arises from registrants' unwillingness to develop the necessary data for crops of limited acreage. It is not economically feasible for them to conduct the various tests and studies required to obtain a Federal residue crop tolerance.

If registrants were able to obtain Federal tolerances for specialty crops, State registrations could be issued expeditiously by either a label amendment or a special local need registration.

Senator **Hayakawa**. Mr. Rominger, may I interrupt you for a moment?

Senator Boschwitz wants to introduce his friend.

He has to leave right away. We will interrupt for a minute.

Senator **Boschwitz**. Mr. Rominger, I thank you and I thank the chairman.

I wish to apologize for the interruption. You have a long, interesting statement. Because of the presence today of the Prime Minister of Israel, all of our schedules have become very strained.

I wanted to spend just a moment, Mr. Chairman, to introduce my friend, Jon Grunseth, who will be a witness later on in the morning and who will testify in turn. He represents the Economic Laboratories which produces a number of chemicals used in California and throughout the country, but he is indeed, as you indicated, a friend and an old friend.

In fact, he at one time ran to be a Member not of this body, but to be a Member of the House of Representatives. I was very active on his behalf during that time. We have been friends and most often allies in the political process since that time and before as well, so we have come to know one another very well over the years.

I certainly have the highest regard for him. He is the vice president of Economic Laboratories, which is a very important employer-industry in Minnesota. It is an important company that was begun in Minnesota and which has grown in Minnesota. It is of the greatest standing in our community.

I hope you will welcome him as he brings the concerns of his fellow Minnesotans as well as his company. He comes with the highest standing both as an individual and the company that he represents.

Mr. Rominger, I apologize for the interruption again, and Mr. Chairman, I thank you for allowing me to introduce my friend, Mr. Grunseth.

Senator **Hayakawa**. You are welcome.

Thank you, Senator Boschwitz. We look forward to your testimony which will come second after Mr. Rominger's.

Thank you.

Please proceed.

Mr. **Rominger**. Thank you.

For many years the Department has worked aggressively with USDA's interregional program 4 and EPA to conduct field studies and laboratory tests necessary to obtain residue tolerances for minor crops. Recently our department proposed to EPA the expansion of six crop groupings. EPA is now in the process of adopting our proposal which will provide tolerances for several speciality crops nationwide.

The statement that California's registration process acts as a barrier to national distribution and advertising of pesticides is also inappropriate. An example is the agricutural herbicide, Hoelon, which was conditionally registered by EPA with an oncogenic effects warning statement on the label due to tumors occurring in certain test animals. Because there was such confusion at EPA and with the registrant as to whether the oncogenic effects would be applicable to humans, California was unable to confirm the material was safe enough for registration. This we were told was disruptive of national advertising and distribution.

In your closing remarks, Senator, it is emphasized that S. 2621 does not preempt the State's authority. In reality, this bill will indeed preempt the State's authority. First, it prevents States from obtaining data prior to the expiration of time required for registration decisions. Thus, forcing States to either deny farmers and consumers products or registration without adequate data. Second, if a State documents the need for data to meet a special local concern, the State must: One, request the data from the Administrator, and there are no timeframes specified as to when the Administrator determines there is a Federal interest; two, if the Administrator determines there is a Federal interest, the Administrator will request the registrant to provide the data which will result in indefinite delays; and three, once the data is developed, there is no guarantee that the State will ever be provided that data.

Without the capacity to obtain up-to-date accurate data regarding the behavior of pesticides as a part of the registration process, it is not possible to assure registered pesticides will perform in a safe and consistent manner under California conditions.

Some chemical companies have made the point that California data requirements are unreasonable. We wonder if anyone in Congress or elsewhere is willing to say it is unreasonable to know how much dermal or inhalation exposure mixers, loaders, or applicators can expect to receive in handling pesticides in toxicity categories I and II. Would anyone be willing to say it is unreasonable for California to ask how long residues will remain on foliage or in soil? These are examples of the type of information needed to establish protective measures for agricultural workers and others who apply pesticides or work in pesticide-treated areas.

Currently, California registration actions are carried out within the 60-day timeframe for products containing presently registered active ingredients and the 120-day timeframe for new active ingredients and major new uses. All registration applications ever submitted to the department have, at this time, received final action except for several new applications which are received at the rate of about 35 per week, and approximately 125 applications submitted without sufficient data to finalize registration where registrants have requested and been allowed an additional specified amount of time to obtain the required data.

Our pesticide registration unit has progressed in accordance with the 2-year implementation schedule initiated July 1980 for carrying out provisions of the regulation changes established on January 4, 1980. We now expect all future registration actions to be managed within the timeframes specified in the registration regulations and that registrants will not experience delays at any point within the registration process.

I urge you to consider carefully the impact of these proposed amendments, as well as the consequences. I urge you not to give in to the pressures of those whose primary motivation for their adoption is the sale of pesticides. Contrast that motivation to those in opposition, whose purpose is to gain knowledge of pesticide hazards and provide the means to promote pesticide use in a safe and effective manner.

EPA has a tremendous task in regulating pesticides and, by and large, does a good job. That task, however, is monumental and very complex. The wide variations in crops, population, soil, climate and geographic conditions throughout the United States make it impossible for a Federal agency to identify each State's potential and unique problems associated with the use of pesticides.

California pesticide program is an integral part of the State's responsibility to promote and protect agriculture. The States must have the right to maintain a responsive registration program that is accountable under State government mandates to protect the health and welfare of their citizens. The proposed amendments to section 24(a) effectively eliminate the State's ability to protect citizens and the environment. If these amendments are adopted, California's populace and its environment will be placed in a very vulnerable and unprotected position.

Mr. Chairman and members of this committee, I thank you for this opportunity to express California's position on the proposed amendments to section 24(a) of FIFRA.

Senator HAYAKAWA. Because you have taken as much time as you have, despite the fact that I told you we are pressed for time and we also have other witnesses, I said we would have to quit at 11 o'clock because of the presence of Prime Minister Begin, so I am going to submit the questions that we have for you in writing and I would like you to answer them in writing.[1]

Mr. ROMINGER. Thank you very much.

Senator HAYAKAWA. Before we hear from our second witness, I would just like to say that as a result of scheduling problems, it is necessary for the afternoon session to start today at 1:30 instead of 2 o'clock.

Would all the witnesses who are here this morning please get in touch with the committee staff before leaving for lunch?

Is Ralph Engel, president of the Chemical Specialties Manufacturers Association here?

Mr. Engel, you are the president of Chemical Specialties Manufacturers Association located where?

Mr. ENGEL. Washington, D.C.

Senator HAYAKAWA. That is the trade association?

Mr. ENGEL. Yes.

Senator HAYAKAWA. You represent a number of firms around the country?

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[1] See p. 128 for questions from Senator Hayakawa and Mr. Rominger's replies thereto.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, ACCOMPANIED BY HARVEY GOLD, CHAIRMAN, CSMA GOVERNMENT AFFAIRS ADVISORY COMMITTEE, PUBLIC AFFAIRS SECTION, AND JON GRUNSETH, SECOND VICE CHAIRMAN OF CSMA

Mr. ENGEL. Yes, sir, good morning, Senator. As you have indicated, my name is Ralph Engel, and I am president of the Chemical Specialties Manufacturers Association.[1] I am accompanied today by Harvey Gold, chairman of CSMA's government affairs advisory committee, Federal public affairs section, and Jon Grunseth, vice president of public affairs, Economics Laboratory, Inc., St. Paul, Minn., and second vice president of CSMA.

The association has a membership of some 425 firms engaged in the manufacture, formulation, distribution, and sale of pesticides to include insecticides, disinfectants, and sanitizers, and detergents and cleaning compounds for household, institutional, and industrial uses. A significant number of these products have pesticidal claims and are, therefore, subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act as amended [FIFRA].

We are here today to respectfully request this committee to merge the provisions set forth in S. 2620, sponsored by Senator Helms, and S. 2621, sponsored by Senator Hayakawa, into a single bill and report it out to the full Senate. Of utmost importance is section 2 of S. 2621 which would amend section 24(a) of FIFRA.

All manufacturers and marketers of pesticide products must, prior to sale, obtain a Federal registration from the Environmental Protection Agency. This step alone is not sufficient to permit sale or use. States themselves each have registration programs and manufacturers must obtain individual State registrations prior to marketing within their borders.

A very serious, anticompetitive problem has arisen in the State of California and already threatens to spread to other States. This problem has to do with the failure to process applications for registration in a timely fashion and with the arbitrary imposition of additional data requirements above and beyond those presently required by the Environmental Protection Agency.

Unfortunately, some 80 to 85 percent of applications for registration have been affected by the State of California's policy requiring the development of new data and additional review of existing data on the same products already registered by EPA and the other States. In requesting such additional data, the State often does not give the registrant any factual basis for the request.

In many cases, the State has held the application for more than 1 year before even asking for additional data. The net effect has been inordinate delays in the registration process. This nonselective, across-the-board approach has resulted in applications undergoing extensive, tedious processing and review, most for no legitimate reason.

Particularly hard hit by this procedure are small businesses and downstream formulators who purchase basic chemicals for formulation into finished products. These firms first depend upon approval of the basic chemicals and subsequent prompt registration of their own formulations to reach the marketplace in a timely fashion for growing seasons and other specialized uses.

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[1] See p. 132 for the prepared statement of Mr. Engel.

Competition has been stymied. Manufacturers have been prevented from getting products on the market—they are virtually locked out from the California marketplace. Consumers and users have been denied useful and effective presticide products which have been granted EPA registrations and which are available in other States.

Initially, the California Department of Food and Agriculture represented to the House Agriculture Subcommittee that there were no problems in its registration systems, as I heard this morning. Subsequently, however, CDFA stated that recent changes in its regulations and efforts to streamline its registration system have solved these formerly nonexistent problems.

We have nevertheless continued to seek information from our membership with respect to registrations emanating from the State.

I have a couple of examples that I would like to bring up.

There are some 30-odd other examples in our testimony. And, Senator, I could spend just 2 hours covering just examples because there are something like 350 that we have on record of current examples

The following is a representative sample of current information obtained from the membership:

1. Application for bathroom cleaner originally submited to CDFA on April 7, 1980; subsequent data package submitted to CDFA, per their request, on July 11, 1980. State requests additional efficacy data on April 7, 1981; new efficacy data was submitted on June 23, 1981; product finally got registered on March 10, 1981.

2. Application for California registration filed on November 26, 1980. The company sent extensive toxicity and efficacy data by courier on December 22, 1980. The company did not hear anything more from the State until March of 1982, some 15 months later, when the State asked for additional data which does not exist and which is not justifiable and does not apply to the problem. The company staff is extremely frustrated and has indicated that the extended delays in the approval of routine registration difficult to understand as no reasons are given for the delays. Time elapsed: 18 months.

As I said, these are but a few examples reported to CSMA by member companies of registration delays caused either by unnecessary, burdensome requests for generation of additional data or by failure of the State to process applications in a timely manner.

THE CALIFORNIA PROBLEM—HISTORY

The problems relating to the abuse of data generation requirements in substantially the same form as originally proposed, the industry sought to obtain corrective legislation in the State legislature. These efforts, however, were unsuccessful.

During all of this time, CSMA has continued to particate in administrative rulemaking procedures within the State to correct the registration deficiencies. Similarly, during congressional review of FIFRA over the past year and a half, CSMA has earnestly participated in developing compromise language for section 24(a). California, on the other hand, has opposed any changes in FIFRA that might correct this problem.

ACTIVITIES IN OTHER STATES

There is a very real concern that other States will move toward implementing similar procedures. We have already seen initiatives in several States that would increase unnecessarily the regulatory burden upon individual registrants seeking State registrations. In addition, there have been recent attempts by political subdivisions below the State level to regulate pesticides contrary to congressional intent. The specific potential problems in other States are set forth in our full statement as well.

DISCUSSION OF THE SECTION 24(a) AMENDMENT PROVISION AS CONTAINED IN S. 2621

Mr. Chairman, we welcome this committee's consideration of amendments to the Federal Insecticide, Fungicide, and Rodenticide Act. FIFRA affects a large number of firms manufacturing, marketing, and distributing thousands of products defined as pesticides. We support this committee's efforts and urge that S. 2620 and S. 2621 be combined and reported out to the full Senate for passage.

I should like to spend the remainder of my time discussing Senator Hayakawa's bill which further clarifies some of the basic provisions of the House amendment.

The legislation, S. 2621, differs from H.R. 5203 in the following areas.

1. It clarifies that a State, but not politicial subdivisions there, may regulate sale and/or use of pesticides or require generation of data. While there is legislative history indicating a congressional intent in this regard, the statute contains no express prohibition.
2. It further refines the term "special local concern" to instances where the State obtains significant factual information which reasonably supports the conclusion that use of any pesticide or device within the State presents a concern relating either to an increased risk of any unreasonable adverse effects on the environment or reduced efficacy.
3. It extends the EPA review function to include special local concern data requests for agricultural products.

CSMA believes that these refinements are both logical and desirable, and we urge this committee to adopt section 1 of S. 2621 in its entirety.

SPECIFIC PROVISIONS OF SECTION 1 OF S. 2621

Contrary to arguments in opposition to an EPA review of State actions, there are precedents in FIFRA for this approach. These are found in section 24(c) pertaining to special local needs, section 27 concerning the State enforcement and section 18 relating to emergency exemptions.

It is surprising that opponents have objected to the incorporation of an EPA overview function in section 24(a) since the three precedents involve consideration of the merits of the State decision, including, always, scientific appraisal of the factual data and, often, risk-benefit evaluation, while the proposed EPA overview in the section 24(a) amendment requires no more than that the EPA Administrator determine if the State request for additional data is arbitrary or capricious.

The bill retains present State authority to regulate sale or use of pesticides and clarifies that such authority rests with States, but not with political subdivisions thereof. This provision is consistent with the legislative history of the 1972 amendments.

Your provision regarding political subdivisions would expressly incorporate this congressional mandate into the statutory language of FIFRA and thereby preclude the necessity for further administrative review or litigation. This clarification, however, in no way precludes cooperation between the industry and local government, and I want to emphasize the last point.

Opponents have argued that the amendment would saddle EPA with numerous data reviews, would increase the Agency's administrative costs, would spawn litigation, and would create yet another layer of bureaucracy. These arguments do not hold up under careful scrutiny. EPA will not spend an inordinate amount of time sifting through State data requests.

The clarification as to when a special local concern may arise will have the effect of reducing the number of potential requests for EPA review since it is more objective and will serve to screen out unnecessary data requests.

One further point with regard to potential lawsuits involving EPA: The only time that a decision by EPA is reviewable in court is when that EPA decision overrules or modifies a State's special local concern data request. Such suit, it should be emphasized, can be initiated only by the State, not industry.

The bill also imposes an obligation on the States to act upon most registration applications within 60 days of receipt or the product is deemed registered. When it pertains to a change in the use pattern or a new active ingredient, action must be taken within 120 days after receipt of the application and all data presently required by the State or, again, registration is deemed granted.

No one member of CSMA can truthfully say they had a registration process of any consequence within 60 days.

The current language of section 24(a) remains intact concerning the State's authority to regulate the sale or use of any federally registered pesticide or device in the State to the extent that such regulation does not permit any sale or use prohibited by FIFRA. That is key, the language in 26(a) is intact, and the State does indeed have the right to regulate the sale of a pesticide.

The new language on section 24(a) does not preempt the State's authority. It does not prohibit the State from banning or canceling a product or denying a registration. It does not in any way restrict or infringe upon the State's right to determine that a special local concern exists.

The amendment does not infringe upon a State's right to ban or prohibit sale or use but is directed solely to instances where the

State requests additional data and to the timely processing of applications for State registrations.

CONCLUSION

Mr. Chairman, CSMA appreciates this opportunity to comment on the Senate FIFRA legislation. We believe the best approach for the committee is to combine S. 2620 and S. 2621 into a single bill and report it out to the full Senate for passage. The paragraph 24(a) provision as it is in S. 2621 will go a long way toward assuring timeliness in processing applications and reasonableness in requests for additional data at the State level.

We will be pleased to answer any questions.

I would like to pass on to Mr. Grunseth, if I may.

Senator HAYAKAWA. Mr. Engel, I am not going to raise any questions for you right now. I will ask you to answer some questions in writing.

Mr. ENGEL. We will be pleased to do so.

Senator HAYAKAWA. We shall pass these on. I am sorry not to do all this publicly, but we are under pressure of time.

Mr. ENGEL. I understand.

Senator HAYAKAWA. I will ask Jon Grunseth, vice president of public affairs, Economic Laboratories, St. Paul, Minn., if he will carry on.

STATEMENT OF JON GRUNSETH, VICE PRESIDENT, PUBLIC AFFAIRS, ECONOMICS LABORATORY, INC., ST. PAUL, MINN.

Mr. GRUNSETH. Thank you very much, Mr. Chairman.

I would like to thank Senator Boschwitz for his very, very kind introduction.

As you indicated, my name is Jon Grunseth and I serve as the vice president for public affairs for Economic Laboratories, Inc., St. Paul, Minn.

We are engaged in the development and sale of products for a wide variety of cleaning and sanitizing uses. Our products line serves the health care, hotel and hospitality industries; and the food and dairy industries; as well as automatic dishwasher detergents, rinse agents, and other specialized household products.

Before I begin, I would like to thank you for giving me the opportunity to appear before you to discuss the amendments to the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA. I will focus my comments on efforts to restrain the excesses of State registration programs.

I would first like to make three initial observations.

One, we are a comparatively large company. For small companies, or rapidly growing companies, who must register many new products to survive in the California marketplace, the burden is several orders of magnitude larger than it is on a large, mature company, like Economics Laboratory.

Two, we are principally talking about nonagricultural pesticides rather than agricultural pesticides. That is an important distinction, one which the Federal Government already recognizes in section 25 of FIFRA. Exposure levels are in ounces rather than hundreds of pounds and use environments are contained and controlled. In addition, many of our products, such as our sanitizers and disinfectants, have substantial positive public health impacts.

Three, this is not exclusively a California problem. The potential exists for disruptions in many other States as well. For example, under existing law New York gives its commissioner power to request with registrations "a full description of the tests made and their results upon which the claims are based."

Similar provisions exist in Texas, Wisconsin, and other States. Other than California, the States are not currently exercising their authority to require exhaustive and duplicative testing data but the potential is there for 50 little EPA's, springing up across the country, totally disrupting all marketing efforts and distribution channels. At least half a dozen States, however, are moving toward adopting systems which would require additional data submissions.

With these thoughts in mind, the California registration system has two major flaws: First, it is time consuming; and second, excessive data is requested.

The time delay problems that we have had and are having in registering our dust mop and cloth treatment product are typical. The product is produced by another company which is also attempting to obtain a registration under its own label. Our registration application was sent on December 14, 1979. We exchanged several minor correspondences checking on the status of our registration, but nothing truly meaningful occurred until we finally received a letter on May 11, 1982, nearly 2 years and 5 months later. The letter, in part, stated: "We received your application * * * on January 28, 1980. We determined the following items of data required were not included." The letter goes on to require some specific efficacy data. The letter closes with the statement: "Your response must be received within 30 days of the above date."

The State, of course, is holding us to a 30-day response time when they have taken well over 2 years to respond to our initial registration.

The amazing thing about this is that they apparently already had the data necessary in their files. Our supplier's June 3 response states, in part, "On December 22, 1981, we mailed you copies of test data in support of label claims." Obviously, the State had not responded to our supplier's December 22, 1981, data submission and subsequently requested from us the same data roughly 4½ months later. As you probably know, the products are idenfified by identical EPA registration numbers, but with our distributor suffix. It would be impossible for the State to not realize that our product and our supplier's product was the same. We are, of course, still waiting for the State's response.

Moving to my second point, California's data requests are excessive by almost any measure. Let me again go through the history of our registration efforts for a representive product. On February 17, 1982, we attempted to register a product named Bac-Flush. This product is an iodine based sanitizing agent, or idophor, used on dairy, beverage, and feed equipment as well as poultry and meat processing equipment. Iodophors have been around as long as the Federal registration process has been around. They are a very, very common type of product.

Despite that fact, we received a letter dated March 10 requesting additional data beyond the Federal data on Bac-Flush. Among other things, they requested "the chemical and physical properties of Bac-Flush." You can well imagine what this request entails. It is simply impossible to list all of the chemical and physical properties of a product, yet that is what the department requested. One of our staff chemists called the department to ask which specific chemical and physical properties the State was interested in. The telephone response was simply that they wanted "the chemical and physical properties" without any real understanding of what the question entailed.

The person who had sent the letter, and who responded to the telephone call, was obviously someone without any technical expertise at all. The request also asked for "the acute toxicity data" and "efficacy data to support the label claim."

The Department of Food and Agriculture had received the summaries of the toxicity and efficacy data which we had sent to the U.S. Environmental Protection Agency. This is consistent with the State's regulations concerning economic poisons which gives the department authority to request summaries of data.

The regulations, however, do not authorize the department to ask for all of the data generated in support of toxicity and efficacy claims, unless the department specifies the reason for each request for additional data. Like the request for the "chemical and physical properties" of the product, these requests appear to be standard procedure whether there is a reason for the request or not. The department is not following its own procedures, thus, unduly complicating the registration process. Given the common nature of this product, they are doing so for no public policy reason.

Economics Laboratory is willing to do its share in guaranteeing that pesticides are safe and effective. It is, however, ridiculous to allow the several States to impede interstate commerce with no public benefit. It is our belief that the language amending section 24(a) in S. 2621 would allow an orderly information gathering process at the State level and would restrict data requests to those which serve some public purpose.

Thank you very much for your attention.

Senator HAYAKAWA. Thank you, sir.

Next we will hear from John Stackhouse, director, Ohio Department of Agriculture, representing the National Association of State Departments of Agriculture. I apologize that we have only about 8 minutes left, and if you want to testify now, please do.

We welcome you here.

STATEMENT OF JOHN M. STACKHOUSE, DIRECTOR, OHIO DEPARTMENT OF AGRICULTURE, ON BEHALF OF THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE

Mr. STACKHOUSE. Thank you, Mr. Chairman.

Senator HAYAKAWA. You understand that you are welcome to continue your testimony this afternoon if necessary?

Mr. STACKHOUSE. If I may, I would like to submit a complete copy of my testimony to you at this time for inclusion in the record, and I will try to make the time limitations that I realize you are working against.[1]

The administrators of State departments of agriculture are charged with the responsibility for implementing State laws relating to regulation of the sale and use of pesticides. In addition, under the provisions for "State primacy in pesticide use enforcement," we have assumed the major enforcement role in insuring that pesticides are used safely and effectively in this country, within the statutory provisions of FIFRA.

The last 10 years since FIFRA was extensively amended in 1972 have been extremely difficult for both EPA and the States.

Since 1972, we have made slow but steady progress in implementing an almost totally new system of pesticide registration, one in which EPA is assigned primacy, with the States authorized a complimentary role under section 24. The States have made strenuous efforts, sometimes under difficult circumstances, to develop a true partnership with EPA; and the record shows that we have worked on behalf of pesticides users and the general public to remove unnecessary regulatory burdens and make the system more efficient, more flexible, and more responsive.

Thanks in part to our efforts, the entire pesticide regulatory process is now developing a forward momentum which, if interrupted for any reason, would be costly to agriculture, industry, and the American public. We, as regulators and administrators, are therefore vitally concerned that any changes in FIFRA preserve the progress we have achieved with great difficulty during the past decade.

I will focus my remarks this morning on a proposed amendment to FIFRA section 24(a) that would seriously jeopardize the integrity of State regulatory programs. This proposal, contained in Senator Hayakawa's bill, would require EPA to become deeply entangled in the process of determining what data a State may request in the course of reviewing a product submitted for registration within that State.

Specifically, the proposed amendment affects a State's authority to require pesticide firms to supply additional health or safety data beyond that required by EPA. State authorities could, under the proposal, require pesticide firms seeking a State registration to submit data in addition to that previously given by EPA. However, if the pesticide firm chooses to challenge the request, the EPA Administrator must assume the role of referee and attempt to decide whether or not the request is arbitrary or capricious.

At the present time, section 24(a) consists of a single sentence. Its meaning is clear and unambiguous: "A State may regulate the sale or use of any Federally-registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act."

The proposed amendment will also require each State to draft new regulations and establish new regulatory procedures that will be more cumbersome and time consuming than the very simple and inexpensive procedures now operating in most States. This regulatory change will mean higher registration fees which, in turn, will be passed back to consumers.

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[1] See p. 141 for the prepared statement of Mr. Stackhouse.

Moreover, the 60-day and 120-day timetables spelled out in S. 2621 mandate some form of conditional or temporary registration procedure at the State level. Ohio State law does not now permit the issuance of conditional registrations, nor, to my knowledge, do the pesticide statutes in most other States.

State laws would have to be brought into conformity with this new requirement.

In recent years, a serious conflict has developed in California. We frankly acknowledge this problem but believe it can be resolved within the framework of existing law. The record shows that section 24(a) has operated successfully in 49 States since its enactment in 1972. Consequently, the proposed amendment penalizes 49 States that have faithfully carried out Congress mandate in order to solve a problem that exists in only 1 State.

It has been charged that, California and six other States have attempted to expand their pesticide programs to exceed or duplicate the Federal registration requirements. To the best of my knowledge, California is the only State that issues additional data requests on a routine basis.

Mr. Chairman, I submit to you that we should not legislate on the probability of other States planning to do this.

Perhaps the strongest argument I can offer in support of our position of no change in section 24(a) relates to the historic rights of the States to manage their own affairs in a responsible manner. Federal preemption has become an all-too-frequent remedy when problems arise at the State level.

Consequently, we in the States have witnessed a gradual but serious erosion of responsibilities traditionally exercised by State governments. The proposed amendment to section 24(a) may be viewed by some as a very minor expansion of Federal power at the expense of the States, but it contributes to a trend.

Section 24(a) strikes a sound workable balance between States rights and the legitimate authority of the Federal Government to set national pesticide policy. State departments of agriculture respectfully request your help in protecting State pesticide programs by opposing any change in section 24(a).

Mr. Chairman, I thank you.

Senator **HAYAKAWA**. Thank you, Mr. Stackhouse, for your very thoughtful presentation.

Before I close this session of the hearing today, I would like to mention that the hearing record will be held open for 2 weeks to allow for the submission of additional information such as any written questions that the staff or the members of the committee may request the witnesses to respond to, as well as the answers and other relevant material that may be submitted.

In addition, the committee has received extensive correspondence on the matter. To the extent that it is appropriate, they also will be included in the record.

Our questions, Mr. Stackhouse, shall also be sent to you.[1]

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[1] See p. 145 for responses of Mr. Stackhouse to questions from the committee and p. 143 for answers to questions from Senator Hayakawa.

We shall reconvene at 1:30 for a continued hearing on this subject.

I think I better recess this session for now and go to see Prime Minister Begin.

The big problem in the Senate is that we all have to be in two or three places at the same time. There should be a law against that.

[Whereupon, at 11 a.m., the committee recessed, to reconvene at 1:30 p.m.]

AFTERNOON SESSION

Senator **Hayakawa**. The meeting will please come to order. The afternoon's program consists of two panels. Bruce Hawley, assistant director of the Washington office, American Farm Bureau Federation, would you take a seat up here; and Jefferson Keith, National Pest Control Association; Robert Fields, director, Regulatory Affairs, FMC Corp.; and Bill McCredie, assistant vice president, environmental affairs, National Forestry Products Association.

Now, I take it that you are presenting your views as a panel, and therefore you will not be presenting formal papers so much as we will start out with your statements, each of you, and then presumably interact, argue with each other or disagree with each other or back each other up; is that the idea of the panel?

Mr. **Hawley**. My expectatation is that there may not be significant disagreement among the members of this panal.

Senator **Hayakawa**. A coalition of intelligent men who agree with each other?

Mr. **Hawley**. Yes, sir; that is the phrase.

Senator **Hayakawa**. Glad to hear all of you.

Mr. Hawley?

STATEMENT OF BRUCE HAWLEY, ASSISTANT DIRECTOR, WASHINGTON OFFICE, AMERICAN FARM BUREAU FEDERATION

Mr. **Hawley**. Yes, sir, thank you.

I would like to submit our statement for the record and simply make a few brief comments if I may, Senator Hayakawa.[1]

The Farm Bureau is a general farm organization representing farmers from across the country. We have approximately 3 million member-families in the United States. Most of the agricultural use of pesticides is conducted on our members' farms, generally by our members. We wish to make a plea to this committee, Senator.

Of the approximately 1½ billion pounds of pesticides used in the United States somewhere between 70 and 75 percent is agricultural in nature. Of the some 1,200 active ingredients registered by the Environmental Protection Agency, less than 100 account for approximately 90 percent of all agricultural pesticide use.

The Agency frequently talks about the preponderance of the job before it, and surely it is a big job to review pesticides to be sure that they are safe and effective.

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[1] See p. 148 for the prepared statement of Mr. Hawley and p. 152 for a letter from Mr. Hawley to Senator Hayakawa of June 23, 1982.

But the job is not unmanageable if the Agency would focus its resources on the agricultural priority needs to assist us, that we might know which products are safe and effective.

Our members have the largest exposure to pesticides of any segment of the public in the United States. Our members are frontline exposure, we handle those——

Senator HAYAKAWA. You handle them or store them?

Mr. HAWLEY. The whole bit. We need to know that those products are safe; we need to be able to rely upon the Federal Government to discharge its statutory responsibility to review pesticides to assure that they are safe and effective. For over 90 percent of the projects that we use, the Federal Government, the Environmental Protection Agency, since 1972 has not conducted the base-line review from the ground up to determine the safety and efficacy on those products as they were required to do in the law.

We are not immediately concerned that there are products out there that pose unacceptable risks; however, continually we are barraged in the agricultural sector by allegations from various quarters that this product is causing environmental harm, that product is causing farmworker illness, and we are not able to turn back to the Environmental Protection Agency and say, this professional, responsible, scientific body of the Federal Government just reviewed that pesticide from the ground up. We cannot point to that with assurance that the product is safe and effective.

It has made us vulnerable to allegations that are difficult to rebut. It has made the industry subject to tremendous costs in terms of litigation and studies, to determine for ourselves, to determine for our own peace of mind, and determine for the public interest, those things which the Federal Government ought to have done and was charged by law to do.

Now, you are going to be requested by various people that testify before this committee to pass a whole variety of additional amendments to this law. The provisions contained in the bill introduced by Senator Helms and by yourself we believe are responsible additions to FIFRA that would expedite the ability of the Agency to discharge its statutory mandate. We urge this committee: "Do not add a lot of other responsibilities to EPA under this law at this time". There are people who are going to ask you to put into the law responsibilities that the Agency serve as a social arbiter of justice and that the Agency oversee the ability of people to file suit all across the country whenever they are unhappy about the way someone is using pesticides.

There are going to be people who will charge that there are farmworkers all over the country being made ill by pesticide use, even though they would not bring in substantive and factual data to support that allegation.

We urge the committee to remind EPA what their fundamental responsibility is: Do not clutter the law with additional responsibilities. We hope you will accept the provisions of the Helms bill, and obviously, that you accept the provisions of your bill, and marry them into a package and report it.

Thank you, sir.

Senator HAYAKAWA. Thank you very, very much, Mr. Hawley.

Mr. Keith of the National Pest Control Association.

STATEMENT OF JEFFERSON KEITH, EXECUTIVE VICE PRESIDENT, NATIONAL PEST CONTROL ASSOCIATION

Mr. KEITH. Thank you, Senator.

Mr. Hawley has amplified very well, I think, our basic feeling, but there are some points that I would like to cover for emphasis.

Our statement has been submitted for the record, and I think you have a copy of it.[1]

Just a brief word about this organization.

We do represent the structural pest control industry, companies who serve homes, food processing plants, food outlets, retail food outlets, eating establishments, hospitals, hotels, warehouses, factories, you name it.

Our comments today basically are for the purpose of emphasizing three points.

One is the concern with the current FIFRA lack of clarity for the State level as the primary regulatory authority for pesticide registration and use. Second is to react to the State regulatory authorities' duplication of the registration costs to pesticide manufacturers which, in turn, increases the cost of the product which we must use in servicing our customers, basically increases overall cost to our public at large. And the third point that we wish to emphasize is to urge continuing support, which we have in the past, for the State programs of certification and training of commercial pest control operators, even more significantly—emphasizing "more significantly,"—than the funds for enforcement.

We looked upon enforcement funds as penalty measures whereas we need to concentrate more on preventive measures such as certification, recertification, education, and training costs.

Our recommendations for correcting these problems have been introduced by yourself and in other aspects of the current legislation being considered, and we urge the strong support of the committee for those points. I do have technical expertise from my staff available if the Senator wishes to question us on any aspect of those; and I would request an opportunity for them to assist me in that area if it becomes necessary.

Senator HAYAKAWA. Thank you.

What is the word "structural" in "structural pest control"?

Mr. KEITH. Any structural facility, contrary to agricultural.

Senator HAYAKAWA. I see.

Mr. KEITH. Home buildings, warehouses.

Senator HAYAKAWA. As opposed to fields?

Mr. KEITH. Right.

Senator HAYAKAWA. OK.

Mr. Robert Fields, director, regulatory affairs, FMC Corp.

STATEMENT OF ROBERT FIELDS, DIRECTOR, REGULATORY AFFAIRS, FMC CORP.

Mr. FIELDS. Thank you, Senator.

I am here testifying on behalf of FMC Corp.[2] FMC is a diversified manufacturer of machinery and chemicals with manufacturing facilities in 29 States and 14 foreign countries. My comments today are made from the vantage of a chemical company that has a longstanding commitment in the area of agricultural chemical research and development. My company is in strong support of S. 2620 and S. 2621.

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[1] See p. 155 for the prepared statement of Mr. Keith.

[2] See p. 161 for the prepared statement of Mr. Fields.

Instead of commenting on the general provisions in those bills, I would like to restrict my comments to one particular section which is most important to FMC Corp. and numerous companies who belong to the agricultural chemicals industry. Specifically, my comments today will be on section 10, the proposed amendments which govern the release of trade secret data.

Yesterday, this committee heard testimony from Jack Early, president of the National Agricultural Chemicals Association, who mentioned the need for section 10 amendments for our industry. He also mentioned the fact that the section 10 amendments which are proposed in S. 2620 were worked out by a coalition of environmental, labor, and industry representatives, and the Environmental Protection Agency. My company feels that the compromise which was worked out in the section 10 amendments is the best that can be accomplished under the circumstances and should receive the support of this committee.

I would like to make a couple of other comments——

Senator **Hayakawa**. Before you go on——

Mr. **Fields**. Yes, sir.

Senator **Hayakawa** [continuing]. Compromise. Would you clarify what the compromise is between, and then——

Mr. **Fields**. The public interest groups, of course, are interested in the release of data for their scrutiny. We are also interested in the release of data for the public to scrutinize when it is made available by the Environmental Protection Agency. What the industry is interested in is protection of that data from getting into the hands of competitors who would use it to get scientific facts or use the data in foreign countries for registration purposes.

So there is a balance of interests between disclosure of data for public scrutiny and the interest of the chemical industry in making sure that it does not get into the hands of competitors.

It is a difficult balance to achieve. We think that the section 10 amendments which are contained in S. 2620 achieve that balance, and therefore the nature of the compromise.

Senator **Hayakawa**. How does it achieve that balance?

Mr. **Fields**. OK, Senator. It makes the data, which we submit to the Environmental Protection Agency, available to the public interest groups, labor organizations, et cetera, but does not allow them to reproduce the data, in toto, in publications. And it restricts competitors in our industry, for example, from requesting the data from the Environmental Protection Agency. There are other provisions, but basically these are the types of controls which are proposed on the data which we submit to the EPA.

Senator **Hayakawa**. Thank you.

Please proceed.

Mr. **Fields**. OK.

One of the requirements of S. 2620 is for the Environmental Protection Agency to promulgate regulations which would implement this balancing of data for the public interest groups and the unavailability of data to our competitors. The House provision, the House bill which was passed by the House Agriculture Committee, contains a statement of principles as part of the statute. The principles which are in that statute were to be the basis for regulations to be promulgated by the Environmental Protection Agency governing the release of data from the Agency.

It is my company's opinion that, although the principles may not have to be contained within the statute, they should be published in the report issued by this committee to give the public interest groups, the Agency, and the industry guidance as to what the regulations should look like when they are finally promulgated.

My last point, Senator, concerns what I think is perhaps an overstated attack on one provision of section 10, and that concerns a provision which gives some added protection to what we call innovative methodologies. I think a fair reading of the statute will convince fair minded individuals that this information is not being withheld from public scrutiny. It is being made available to scientists and can only be maintained as innovative methodologies for 5 years.

I would also like to emphasize that, if requested, a company is required by the statute to make a summary available for public disclosure.

This debate on innovative methodology occurred yesterday, and I think we will hear more about it this afternoon from the next panel. But I would urge all interested parties to take a closer look at S. 2620, specifically section 10. I think it is a fair compromise which has been worked out.

That concludes my comments, Senator.

Senator **Hayakawa**. Thank you very much.

Now, Bill McCredie, assistant vice president of environmental affairs, National Forest Products Association.

STATEMENT OF BILL McCREDIE, ASSISTANT VICE PRESIDENT, ENVIRONMENTAL AFFAIRS, NATIONAL FOREST PRODUCTS ASSOCIATION

Mr. **McCredie**. Thank you, Senator.

I am here representing the National Forest Products Association, who in turn represents more than 2,500 companies in the United States and Canada who are involved in the growing of trees and the production of wood products. We have submitted written comments to the committee and I would like to ask that those comments be made a part of this record.[1]

Senator **Hayakawa**. It will be. So ordered.

Mr. **McCredie**. I am here today to highlight some of our concerns and to answer any questions you may have. In contrast to the farmers, the forest managers of the United States use less than 1 percent of all pesticides that are manufactured in North America. In spite of that low usage, it seems that the forest industry, forestry in general, draw about 85 percent of the controversy related to pesticide use. A very high percent of the public controversy is related to forestry use of pesticides.

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[1] See p. 163 for the statement of Michael C. Farra inserted by Mr. McCredie.

A case in point is the gypsy moth spraying in Oregon recently around the town of Salem, where there were several court actions taken against the application of the pesticide Sevin-4-oil for gypsy moths. Our goal in testifying and looking at these bills is toward a more objective scientific based regulation and implementation of FIFRA. To that end, we are especially supportive of the changes in your bill which would make section 24(a) of the act, specifically the provisions that would prevent subdivisions of States, counties, from regulating the sale or use of any federally registered pesticide. Four counties in California have tried to develop regulations to ban the use of certain forest pesticides.

In the town of Index, Wash., for instance, with a population of only 200, they have attempted to establish such a ban regarding forest pesticides. These ordinances are inevitably thrown out by State courts or overruled in referendums, but valuable time in a short spraying season can be lost for forest managers. Pest problems invariably extend across county lines, and county governments are ill equipped to make the scientific risk and benefit decisions of pesticide use. So these controversies usually involve emotional and/or anecdotal information.

The changes to section 24(a) in your bills, Senator, would also go a long way toward shortening the time it takes a federally registered pesticide to obtain State registration. The forest industry supports the time limit for State consideration of a pesticide application, and we also support the limitations on States that allow them to request only data that has a reasonable basis for their determination of whether or not to register a pesticide.

There has been considerable discussion before this committee about adding a private right of action to sue in Federal court to prevent an alleged misapplication of a pesticide. The forest industry vigorously opposes such a provision on the grounds that it potentially could be abused by those seeking to halt a forest pest spray project by bringing frivolous legal action that would result in missing the appropriate time for application.

Moreover, adequate remedies, we believe, already exist under both State and Federal law.

Chairman Helms' bill proposes to add a provision to section 12 of the act which would protect the employment status of an employee who reports a violation of the pesticide law. Such a provision has the potential for fostering a hostile and suspicious employee/employer relationship. It also has the potential for abuse in that an employee could make unfounded accusations concerning pesticide use and thereby insulate himself from appropriate adverse employment action.

We do not believe there is any evidence in the forest industry that any employee has been discriminated against for exercising his rights under FIFRA. And let us also mention that the House committee that has passed FIFRA amendments has made an unnecessary provision even more burdensome by involving the Secretary of Labor in its enforcement. The EPA Administrator is charged under FIFRA with protecting health and the environment. Involving another Federal agency could create yet more bureaucratic nightmare. FIFRA is an important law in that it helps to safeguard health and the environment while waiving the considerable benefits from pesticides.

Science is of course an important part of that process, and the forest industry applauds the reauthorization of the scientific advisory panel in the proposed amendment to section 25(d) of the act.

Overall, the forest industry supports the efforts of this committee to maintain the current purposes and workability of the law.

I thank you, Mr. Chairman. I would be happy to answer any questions.

Senator HAYAKAWA. Thank you very, very much. I do have some questions.

Mr. Hawley, let me start out.

Can you elaborate further and perhaps cite some examples as to why farmers are opposed to the idea of providing for private rights to sue under FIFRA?

Mr. HAWLEY. Apparently in every State in the country under common law any individual that is threatened or harmed by another's actions, including by the use of pesticides, can go to court in a minute, seeking equitable relief, whether it is damages or whether it is injunctive relief. Whatever kind of relief is appropriate is readily available in the courts. So we do not believe that it is a necessary provision.

Second, it is almost certainly going to be a provision that would be subject to gross misuse in the event that it were incorporated in the law. A similar provision under another Federal statute deals with the relationship between farmers and migrant workers. In the State of New Jersey, the New Jersey Farm Bureau established a migrant housing facility that was rented by a contracting agency for Puerto Rican workers going to work in the State of New Jersey. They had over 125 separate pieces of litigation filed against them. The last time I had checked, about three-quarters of them had been litigated; none of them had been ruled against the Housing Association. They were all litigated separately. It cost a half a million dollars in attorney's fees to defend the operation.

The workers did not get a thing; they did not get a penny. All the workers got out of it was they lost their jobs, not because they were fired, but because the people went out of that business and the jobs dried up.

The purpose of those suits was not to bring justice; it was to harrass. The suits were filed by the Federal Government through the Legal Services Corporation. We did not like it, and we do not want to do it again under FIFRA.

Senator HAYAKAWA. And the lawyers representing the workers—or misrepresenting them—they are paid by Legal Services Corporation?

Mr. HAWLEY. In that instance, that is correct; yes.

Senator HAYAKAWA. And the workers, did they have a complaint?

Mr. HAWLEY. Some of the suits involved disputes in wages of $12 to $25. I do not know if that is a complaint or not.

Senator HAYAKAWA. Mr. Hawley, you testified you represent many farmers who are major users of pesticides, and thus have frontline exposure to pesticide risk. And as you know, there is considerable controversy about the disclosure and there are charges that scientific oversights of EPA would be substantially damaged if these provisions are adopted.

Now, why aren't farmers concerned about these provisions?

Mr. HAWLEY. We do not make any pesticides; we do not register—we do not have any proprietary interest in that particular issue. At this juncture, our position is that we are relying upon the coalition result, the issue that Mr. Fields spoke of, the coalition of labor in environment and industry. They had come through on a position with relation to this issue that they feel would protect each of their interests.

We are not prepared to say that it is a good position or a bad position, but rather to say if everyone can agree with it, if it is something that will cause the law to work, if it is something that will remove the stumbling blocks to registration of pesticides, then we are for it.

Senator HAYAKAWA. Mr. Fields, yesterday there was testimony suggesting that the innovative methodology in technology lacked an adequate record justifying a need for such provision.

Can you tell me just exactly what type of provision this includes and why are these data so important to your industry?

Mr. FIELDS. Yes, I would be happy to, Senator.

I guess as an initial comment, the only data right now which are absolutely protected are trade secrets. There are really three pieces of data: they concern inert ingredients, the percentage of inerts and the manufacturing process. Everything else is disclosable under section 10.

However, chemical companies do spend quite a bit of money and time developing what we call innovative methodologies or technology dealing with how to analyze a compound, how to analyze its chemistry, environmental chemistry, et cetera. What we are talking about are methods, chemistry methods, analytical methods used in a laboratory. These can take years to develop, can be worth millions and millions of dollars.

If a particular company has developed one of these methods, we think it is entitled to protect that method for its own use and should not have to share that particular method with its competitors. The provision which is contained in the bill, however, does make these innovative methodologies available to the public under protection which basically says that they can only go to qualified scientists. These scientists can discuss it, and can talk to each other about it.

As I said earlier, summaries of methodologies are available for public disclosure. It is a matter of advanced technology, and we would like to treat that as protected data, but at the same time share it on a reasonable basis with public interest groups.

Senator HAYAKAWA. There is a vote on, but I do not have to leave for another 5 minutes. Before I make my vote, I am going to call on the next panel.

I would like to ask the four of you if you have any comments to make on this testimony of the other three.

Mr. KEITH. Well, I would like to add one point of emphasis to the forest products comments regarding the activities of political subdivisions. And the point I want to emphasize is, we think it was made very clear in the congressional hearings, previous congressional hearings, that the intent of Congress was that political subdivisions do not permit regulations of pesticides by those political subdivisions despite that intent and implication. There have been several States who have—or political subdivisions of several States—who have attempted to regulate and control the use of pesticides to—and two other States have issued specific legal documents indicating that such regulations were not legal.

And that is in Massachusetts and New York.

So in view of that intent, the implication and the decisions of two major States, we think the Federal legislation itself should make that point clear and urge the support of your amendment.

Senator **HAYAKAWA**. Thank you.

Any other comments on each other's statements?

I was wondering about the enormous percentage of the litigation that has to do with use of pesticides in forestry. You were saying that, were you not?

Mr. **MCCREDIE**. Yes, sir.

Senator **HAYAKAWA**. It frightens people more than other things?

Mr. **MCCREDIE**. There is more of a controversy revolving around the forest use of pesticides because people recreate, live and grow other crops in the forests. It just has drawn a lot of heat. Also, the Federal managers of forest lands are susceptible to suits under NEPA, and that draws quite a bit of controversy to forest spraying by Federal land management agencies.

Senator **HAYAKAWA**. My staff member said marihuana.

How does that come into the picture?

Mr. **MCCREDIE**. Well, according to the States of California and Oregon, that is one of the major crops that is grown, and it is very susceptible to the use of herbicides in forest lands that may be around where the marihuana is grown.

Senator **HAYAKAWA**. When you smoke this marihuana that has been sprayed with herbicides, it does dreadful things to you?

Mr. **MCCREDIE**. I don't know, sir.

Senator **HAYAKAWA**. I am sure you must have heard about the lawsuits and reasons that are given purporting to say that this is dangerous for that reason.

Mr. **MCCREDIE**. Well, I have heard it on the use of paraquat.

Senator **HAYAKAWA**. Yes.

Mr. **MCCREDIE**. But I have not heard it as a health-oriented accusation in forest spraying.

Senator **HAYAKAWA**. The fact that pesticides used on forests arouse so much public indignation is a piece of news to me.

Aren't people equally concerned about the poisons that are sprayed upon the produce that they eat?

Mr. **MCCREDIE**. Well, food use does not seem to draw the same level of public controversy from the media as forest use does.

Senator **HAYAKAWA**. In California, we have these alleged natural foods and natural vegetable stores all over the place that charge twice as much for a stalk of celery on the ground that they have been used with completely natural organic methods of growth and no pesticides, no insecticides have been sprayed on them, and so you can eat these safely without any chemicals getting in your system, et cetera, et cetera, even though it is a fact we are all made of chemicals anyway.

Mr. HAWLEY. I think, Senator, perhaps it depends a little bit on where you are coming from. Mr. McCredie is naturally concerned about the forest product industry; they have a lot of controversy and publicity, likewise, specific agricultural commodities have run into the same problem. You recall the use of ethylene dibromide that was in the Mediterranean fruit fly area. There was substantial controversy about a negligible residue that they can barely detect. I think the controversy arises wherever someone feels they can make some political hay out of it.

Senator HAYAKAWA. That is exactly what happens.

I am going to recess the hearing for 10 minutes while I go vote. Thank you.

[Recess from 2:10 to 2:25.]

Senator HAYAKAWA. Well, we shall return to our panel.

The panel this afternoon consists of Maureen Hinkle, who represents the National Audubon Society; Jay Feldman, representing the National Coalition Against the Misuse of Pesticides; and Ralph Lightstone, California Rural Legal Assistance Foundation testifying on behalf of the Migrant Legal Action Program; accompanied by Nate Karch.

Welcome to all of you.

Now, my schedule involves a meeting with the Ambassador from Liberia—this is a great job; your mind has to jump up—just today, since 10 o'clock, agricultural pesticides, to Prime Minister Begin; what is going on in Lebanon, back to agricultural pesticides, to a vote on an amendment to the budget, back to pesticides, then I have got to go and visit the Ambassador of Liberia. And I shudder to think what comes after that. But I would hope that we can finish by 3 o'clock with this.

If it leaves any of you with unanswered questions or things that you want to say that you did not manage to get said, please do not hesitate to write in. And if there are questions left in my mind, I will write to you and we will exchange correspondence on the subject after this meeting is over or at least in the subsequent 2 weeks.

So, Maureen Hinkle, will you start out; or are you going to act as a panel and each of you make a short statement and then interact with each other? Is that it?

STATEMENT OF MAUREEN HINKLE, NATIONAL AUDUBON SOCIETY

Ms. HINKLE. Yes; that is fine. Thank you, Senator Hayakawa.

I represent the National Audubon Society, for whom I have been working for 1½ years. Before that I was with the Environmental Defense Fund, watchdogging implementation of the pesticide law for 10 years.

I will summarize my statement.[1]

We recognize the need to retrieve costs of research and development for pesticides. This makes it important for companies to obtain a market as quickly as possible, and to sell as much as possible within the patent life. With this kind of profit incentive, it is predictable to have the kind of legislation embodied in the bills before us today.

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[1] See p. 167 for the prepared statement of Ms. Hinkle.

The number of pesticides—1,500 active ingredients and 50,000 registrations—is an indicator of the interest vested in registration, as is the 70-percent rise in production since 1970, the year EPA was given the responsibility for pesticide registration.

Also prevalent is the goal of screening chemicals for pesticide use; the desired goal is as close to 100 percent target kill. This kind of search, however, brings the goal of maximum target kill into direct conflict with the environment surrounding the target pest, which includes beneficial life refuges, estuaries, people living in agricultural areas, and people living near forested areas.

We respectfully suggest that these directions need examination. Chemical companies should ask how to test and select for effective chemicals that will cause the least ecological disruption. If it means a chemical must be used only every 2 years to prolong effectiveness, legislation could be sought that might lengthen patent protection to allow longer years of safe use rather than a decade of disruption and conflict. We would encourage a search for innovative ways to protect the environment and the investment of chemical companies in such a search.

Much has been said today about innovation. We would like to emphasize that we are in favor of genuine innovation. At a time when we are increasingly concerned with productivity, it would seem appropriate for Congress to require long-term quality research on interactions of pesticides, pests, and productivity.

We are concerned that productivity is rising at a lower rate, and that quantities of pesticides used has increased by 70 percent.

We need to look beyond the short term and often cutthroat profits. For the regulators, there is a need for long-term experiments in order to measure residual or cumulative effects of pesticides in the environment.

For the short term, since we are looking at this legislation before us, we have several specific recommendations: First, to strike section 10(a)(1)(b), "Innovative Methodology"; and to strike section 3(c)(8), which is unnecessary. It is an interim review appealable to the district court, which we already have. And we would ask for six amendments which we believe would balance this special interest legislation that is embodied in the two Senate bills we have today.

Two amendments deal with inerts. The first would require regulations for inerts testing, and the second would disclose the identity of inert ingredients to the public.

A third change would simply give environmental and interested parties standing by changing one word, from "a" to "any," so that instead of "a interested party," it would be "any interested party" who could sue.

The fourth change would give a private right of action under section 16(e). A fifth in section 25(f), mandates farmworker standards, which in the House version will be done only if EPA finds it necessary. The final change, simply an editorial one, and I believe an oversight, a phrase involving production of pesticides that should have been included in section 10(h) and 10(i) instead of only in section 14.

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This would mean that should I be paid $50 or some amount of money for publishing an article which incorporated information obtained from EPA, I could not be put in jail and fined damages for having used the information for "commercial" use. The penalty should apply to a person only if used for registration, sale, or distribution of a pesticide, and not for a simple fee for an article.

The section we would like——

Senator HAYAKAWA. Wait a minute; wait a minute.

You are talking essentially about trade secrets, are you not?

Ms. HINKLE. It is disclosable information. Section 10 provides for disclosable and nondisclosable information. It is the disclosable information that, if used for commercial advantage, we could be fined pursuant to section 10 (h) and (i). And I simply want this clarified. It is an editorial change, really.

Senator HAYAKAWA. I see. But if someone else reads this article after it is published and uses this, then what?

Ms. HINKLE. It is unlikely that would happen.

Senator HAYAKAWA. Everybody searches literature if they are looking for——

Ms. HINKLE. Essentially, most of this information is already in the literature anyway. And it was my understanding that we had agreed to the insertion of this phrase in four places in the——

Senator HAYAKAWA. What is the phrase?

Ms. HINKLE. "Involving production, registration, distribution, or sale of a pesticide," right after "commercial use." This phrase is already in the language twice in section 14, and it was our understanding that it was to be in four different places. I have the handwritten understanding that this was going to appear in four different places. It is really just an editorial change.

Senator HAYAKAWA. The intention is to make this information publicly available to those concerned; is that right?

Ms. HINKLE. According to the 1978 language, the congressional intent was to disclose health, safety, and environmental data to the public to enable independent scrutiny and studies that were submitted to EPA in support of a registration. EPA relies on the studies conducted by the registrant in order to approve the registration. And in 1978 it was determined that health, safety, and environmental information should be disclosed to the public.

And the information that should not be disclosed would be the identify of inerts, manufacturing process, production quantities, because Congress determined such information to be a commercial disadvantage to reveal, to disclose.

Senator HAYAKAWA. You believe that the registrant is sufficiently protected against business competitors?

Ms. HINKLE. I am sorry?

Senator HAYAKAWA. You believe that the manufacturer or processor is sufficiently protected against business competitors?

Ms. HINKLE. Yes, for manufacturing processes there has never been a disagreement, that that should be disclosed.

Senator HAYAKAWA. You want to say something?

Mr. LIGHTSTONE. If I could interject one thing here——

Senator HAYAKAWA. This is a panel, so you can all feel free to speak.

Mr. **Lightstone**. The reason that the 1978 law protected the manufacturing process in inerts but not safety and efficacy studies was that it recognized the commercial investment in those studies was protected by two things; the patent laws by which a company has an exclusive right to sell the product, and the exclusive use periods that were put into section 3. Between those two protections, the investment of the company in the safety and efficacy search was protected, and that is why Congress did not object to those studies being made available.

A safety study has no economic value in and of itself to any competitors if they see it other than the fact that it could be used for registering a pesticide product at the Federal level. The Patent Act in exclusive use periods prevent that from happening.

Senator **Hayakawa**. Thank you.

Do you want to proceed?

Ms. **Hinkle**. Let's see. I was on innovative methodology which is the section that we very strenuously object to because we believe it creates a precedent that should have far greater scrutiny and investigation than the hearings today and yesterday. I would like to touch upon how the concept of innovative methodology was first brought up in the House subcommittee hearings.

It first came up on July 22 of last year. At that time the representative from Monsanto presented a problem to the subcommittee. He explained that they had invented a method of analyzing the product in their environment. This method was called radiosynthesis. Which would not qualify as a trade secret. The 1978 language declared metabolism and environmental facts data to be releasible.

The representative of Monsanto felt his company should be able to retrieve the costs of developing innovative methodology. This concept did not find its way into the House bill, but appeared in the substitute bill which was written by EPA and the National Agricultural Chemicals Association. And it replaced the House bill, printed on December 4.

The substitute bill is the first time that innovative methodology appeared in the legislation. Once introduced we submit that it became a useful device in which to fold other kinds of data that industry believed would fall into the 1978 definition of disclosable data, but which they preferred to withhold. Thus it was never adequately defined, and today it was not defined, even though it was requested. And it remains inadequately defined since keeping it broad and variable, it can included a multitude of items.

Audubon submits that today we are dealing with a great many new chemicals, brandnew molecules with no idea of how they work or what they are. If anything, we need a greater understanding of their fate in the environment. We cannot afford to deny society the knowledge of how these chemicals work in the environment.

In regard to inert ingredients, we prefer that rather than the placing more information in the trade-secret category, that we take more information out of the trade-secret category. And that is why we feel that inert ingredients be disclosd to the public.

Senator **Hayakawa**. Shall we go on to the others, because you can bring in the rest of your material as it occurs in context.

Ms. **Hinkle**. OK.

Senator **Hayakawa**. Because we have limited time and three other speakers.

Mr. **Feldman**. Thank you, Mr. Chairman. I will make my comments brief and ask that my prepared statements be inserted in the record at this time.[1]

Senator **Hayakawa**. Yes, they shall be.

STATEMENT OF JAY FELDMAN, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. **Feldman**. I represent the National Coalition Against the Misuse of Pesticides, which is a broad-based network of organizations and individuals from 50 States, including family farmers, farmworkers, beekeepers, chemical workers, and urban and rural residents all concerned about exposure to pesticides either through their employment, as consumers, or as neighbors of dumpsites, sprayed fields, forests, or rights-of-way.

You may be aware that when Mr. Helms introduced S. 2620, he noted that a number of problems had been encountered by the pesticide industry, a number of problems relating to the release of health and safety data on pesticide products, and that this release creates a disincentive for the chemical companies' investment in product development.

In the interest of balance in these hearings, Mr. Chairman, we would like for a moment to focus on the very serious problems that the public and pesticide users have encountered. The health and environmental problems faced by the public are not addressed by S. 2620. And in fact, what this bill does, in our perspective, is to throw the precarious balance of this act dangerously off center.

Our overriding concern—and I hope to just give you a real brief overview—relates to public and worker health and safety, and what the exposure to dangerous, potentially life-threatening, pesticides really means. I would like to outline that briefly, take a moment to go through the points, and then take 1 more minute to give you an eight-point solution as we see it in terms of reauthorizing FIFRA.

There are 45,000 cases of pesticide poisoning in this country documented by EPA. This is a real problem. Involuntary exposure has been cited as perhaps the central health public issue of the 1980's. Studies report pesticide exposure incidents, chromosome aberrations, infertility, miscarriage, and other adverse effects on reproduction associated with exposure to pesticides.

Six types of cancer pose greater risk to the farm population than to city dwellers as pointed out in the 1981 study at the University of Iowa, and increasingly we are seeing wildlife, milk, and the Nation's ground water in case after case contaminated with pesticides.

I hope and I urge you, Mr. Senator, to instruct your staff to carefully go through a number of GAO studies which have tremendous bearing on these proceedings. One is a GAO report in 1980 which talks about tolerances to pesticides on food and feed products. It is clearly suggested in that report that the basis for many tolerances granted by the Food and Drug Administration, with EPA providing

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[1] See p. 177 for the prepared statement of Mr. Feldman.

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data and levels, are obscure, that the data is not adequate, and that we are lacking in long-term studies which show whether a pesticide causes chronic effects, such as cancer or birth defects in animals.

EPA for years has been accepting faulty health and environmental test data; 22,000 chemical safety tests have been called into scrutiny. And as a result, although there is not agreement in the scientific community as to the reasons, there are more than 800,000 cases of cancer or will be this year, and 3 out of every 100 children born in this country suffer what CDC, Center for Disease Control, calls serious birth defects. That is not something that should be dismissed summarily.

Also, Mr. Senator, please instruct your staff to look at the 1971 GAO report on pesticide use and lack of enforcement across this country. We have a tremendous problem there.

We also have a problem with EPA circumventing the normal routes of pesticide registration through the use of the section 18 [FIFRA] emergency exemption and other special provisions. This situation is dangerous, we submit, and we believe you can document a dramatic rise in these "emergency" cases over the past year.

There are social and economic costs that suggest 40 cents of damage out of every dollar spent on pesticides in this country.

Now, in terms of a minute on S. 2620, let me be clear that despite what you have heard from the industry panel, there does not exist a compromise proposal in S. 2620. We are keenly concerned about the quasi-trade secret category of health and environmental data defined as innovative methods or technology and what that means to independent scientific peer review. Right now the industry is reviewing toxaphene, and in debating that argument, BFC Chemicals, Inc., says that the hazards——

Senator **Hayakawa**. What is the name of the chemical?

Mr. **Feldman**. Toxaphene, the most widely used insecticide in the United States.

The way that EPA defends that model is to say it appears in state-of-the-art literature. We submit, Mr. Chairman, that the only way to in fact determine whether a methodology is valid is to insure that it withstands the scrutiny of scientific debate and published scientific debate. The debate on toxaphene suggests that it creates thyroid carcinoma in rats and gets in our food chain. Part of the data is based on a model that is being scrutinized by the scientific literature, has been scrutinized by the literature, and should be scrutinized by the literature, whether defined as innovative or not.

I request that letters on this very point from Harvard, Cornell, and an employee of the National Science Foundation, as well as scientists at the University of Florida-Gainesville, be placed in the record.[1]

As stated by Ralph Lightstone, we feel that patent law and exclusive use periods, which would be significantly lengthened to 15 years, under S. 2620, should be enough to protect the industry in-

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[1] See pp. 192-195 for the letters referred to by Mr. Feldman.

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vestment in product development. Let me briefly get to our eight points.

One, we feel that if we increase fines and data submitter penalties for those obtaining and/or using health and safety data in furtherance or a commercial purpose, involving the production, registration, distribution, or sale of a pesticide, that we can accomplish the industry's concerns and meet their needs.

We submit, No. 2, that all inert ingredients be disclosed. And I would like to at this time place in the record a study presented to EPA by Potomac Research Associates which points out over 50 class 1 and class 2 inert ingredients that are contained in pesticide products on the market today and remain secret ingredients. We ask that the list be placed in the record, Mr. Chairman.[1]

Senator HAYAKAWA. OK.

Mr. FELDMAN. We ask for six other points, one in terms of redefining unreasonable adverse effects; we want and hope that you will consider granting standing to persons whose interests are adversely affected by EPA's rulings or cancellation actions.

We would like to see workers protected who allege violations of the act. We would like to allow States flexibility to impose requirements on labeling and packaging and would like to insure the issuance of regulations providing for safe working conditions, documentation of pesticide applications, requirements for storing and warehousing, disposal of pesticides and pesticide containers. And we would hope you would seriously consider section 16 amendments which will insure that this act be one that is self-enforcing through a citizens suite provision, which is now contained in the Clean Air Act and Clean Water Act

Finally, I will leave to the other witnesses to discuss section 24 and other scientific issues related to 10. But we would like you to please reconsider section 24 changes and recognize that it has severe implications to States rights and States ability to protect its citizens.

Thank you for the opportunity to present our opinions on these bills before you and the need for an effective pesticide law.

Senator HAYAKAWA. Thank you very much, Mr. Feldman.

Can we hear from you, Mr. Lightstone?

Mr. LIGHTSTONE. Thank you, Senator.

First of all, I would like to offer my written testimony for the record.[2]

Senator HAYAKAWA. It will be so entered.

STATEMENT OF RALPH LIGHTSTONE, CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION AND FARMWORKER JUSTICE FUND, INC., ON BEHALF OF MIGRANT LEGAL ACTION PROGRAM

Mr. LIGHTSTONE.The American Farm Bureau today made a statement that we think is crucial and that we agree with. That may sound a bit unusual, but they have identified what is the most crucial problem in the area of national and State pesticide regulations, and that is the fact that the key agricultural pesticides that are used in California and this country have not been tested or evaluated under current testing and evaluation requirements.

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[1] See p. 194 for the study referred to by Mr. Feldman.

[2] See p. 196 for the prepared statement of Mr. Lightstone.

They have been grandfathered in from past decades under USDA registration. That problem we agree with the Farm Bureau is the one that is crucial and needs to be solved.

None of these bills will solve that problem. In fact, we think that some of the provisions in these bills are going to exacerbate the problems that they are concerned about. One of the reasons that they stated that they wanted the pesticides tested and evaluated in the current standard is that they want to obtain confidence for themselves and for the public that these products are safe and efficacious.

The best way to assure confidence in the use of pesticides is to make sure that the tests that are done on them are made public. In the past—and up to today, safety and efficacy studies have not been made public, despite the orders of Congress in 1978. The reason for that has been constitutional challenges to the statute that Congress enacted in 1978 by the pesticide industry. I would predict that if either H.R. 5203 or the section 10 changes in section 2620 are enacted, we will see a new wave of pesticide litigation and safety and efficacy studies will not be released for years.

And I think that is no way to inspire the public confidence that we all seek for to sort out which pesticides——

Senator HAYAKAWA. Is there any program of reevaluating those ingredients in pesticides which were grandfathered in after the 1972 act?

Mr. LIGHTSTONE. There is a program at the Environmental Protection Agency and another one in the State of California. The EPA reports it is going to be decades before that process is completed.

The State of California has even less resources to do that. Congress in 1972 ordered the EPA to do it within 5 years. And the process has barely begun.

Senator HAYAKAWA. OK. Thank you.

Mr. LIGHTSTONE. The data gap is what we call that problem, and the data gap is the actual source of the complaints about the California State program that has prompted the efforts to change section 24. I would like to explain for a minute how that process worked.

In 1980, California adopted a series of regulations that required from that time forward in time, pesticide registration applicants to supply summaries of the Federal data on the pesticides as well as some additional State data. It brought pesticide registrations, even of old products, to a halt in California and created a huge logjam. The reason for that was that all of these pesticides had been grandfathered in for years, and the testing had never been done. And it created a logjam that was unfair to new applicants.

What happened was, say 30 companies had registrations of toxaphen, in California prior to 1970. Along comes a small company, Company No. 31, and says, we want to sell a product just like the other 30 on the shelf. The State, because it chose that date to begin requiring the data, said, well, where is all the Federal data requirements? And the company did not have it and could not generate it.

And it might be a small company as opposed to the huge pesticide manufacturers that were already grandfathered in.

So that process had continued for quite some time and created a huge backlog of data. The problem was the data gap was blocking registration. And California could not solve the data gap that way.

So a few months ago the State yielded to the EPA practice of continuing to grandfather new products. And what Mr. Rominger testified to this morning is with State regulation changes that occurred a few months ago, the logjam is broken and all of those products are allowed in California. We grandfathered new registrations of old products just like the old ones.

We have lifted the logjam, but the data gaps still exist.

Maybe I ought to yield to my colleague before going on.

Mr. KARCH. Thank you.

Senator HAYAKAWA. Mr. Karch?

Mr. KARCH. Yes.

I will just briefly describe what is in my statement, and I would appreciate it if my statement could be placed in the record.[1]

Senator HAYAKAWA. It will be so ordered.

Mr. KARCH. I guess I really only have time to describe to you what I have tried to do in my testimony.

Senator HAYAKAWA. I am going to have my staff members telephone my office to say I will be 10 minutes late so you can finish.

STATEMENT OF NATHAN J. KARCH, PH. D.

Mr. KARCH. Oh, thank you very much.

The first statement I have to make is probably much more important to my career than to the issue here, and that is that the views I present here today are my own and not necessarily those of Clement Associates, a consulting firm that specializes in risk assessment, or of Howard University, where I teach part time.

In my statement I outline my professional career to try to give you an idea of how I have tried to understand some of the issues being considered here today. I have considerable experience in the regulation and assessment of toxic substances, some experience with the problem of confidentiality, and probably most important, a great deal of experience in assessing risks—risks of cancer, reproductive damage, and nerve damage. I have come today to try to give you an idea of how the data that would be covered by the proposed amendments to section 10 fit into the kind of work I do in assessing risks. I do this to try to characterize the importance of these data to the public interest in keeping them accessible.

In my testimony, I also try to raise some practical problems or potential problems that I see with the provisions. And if there is time I will describe those. If not, I commend these to your staff to review, and I would be happy to answer any questions about them.

In doing a risk assessment, it proceeds somewhat in stages. The first is a hazard evaluation. This is really an investigation of the inherent toxicity of a chemical so one would look at the main pesticide ingredients, any of the active ingredients, any of the contaminants and also look at degradation products and metabolites; in other words, to review the products that arise from changes in the body or in the environment. Once one has the identity of these chemicals, there is a search to find any toxicity associated with those chemicals.

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[1] See p. 203 for the prepared statement of Mr. Karch.

This might cover studies in animals or exposed humans or in other kinds of testing such as bacteria.

The next stage is to look at exposure assessment, to evaluate the population of concern—pesticide workers or consumers of pesticide treated fruit crops—and evaluate the route, frequency, duration of exposure, and also the size of the population affected, and any special characteristics. These are then combined in the risk assessment. The risk assessment is really an estimate of the degree to which these identified hazards will be realized in the population of concern.

The goal is to quantatively estimate these risks. And this administration has emphasized, and EPA is now emphasizing, more of a need to be quantitative in these kinds of risks. In order to do quantitative estimation and have it be meaningful, however, one needs reliable data. And what I have tried to do in my testimony is run through some of the examples of the level of detail needed in order to do a meaningful risk assessment.

Often one comes across conflicting data or apparently conflicting data. Sometimes it is merely a question of the power of a study to detect an effect; for example, if one study shows no effect and you compare it to a study that shows a positive effect, it may be likely, and we have found in many cases, that the one that gave rise to a positive effect was a much more sensitive test. Therefore, there is no real conflict.

Other times it is a question of the nature or chemical purity of the substance under test. In one case, an impure substance is tested and there is toxicity, but then when the pure chemical is tested, there is no toxicity. Again, very detailed information on the identity of the chemicals is very important.

Sometimes it is not easy to resolve conflicting data or to analyze the studies in question, and a great deal of information has to be brought to bear in doing the evaluation.

The section that is under consideration in section 10 to expand confidentiality to innovative methodologies encompasses data on product chemistry, residue chemistry, and metabolism that are critical in doing a risk assessment. I do not deny that this kind of data may have a major financial advantage to a company; I am not an expert in that. But I do know that they are really very critical to the problem of risk assessment.

Senator HAYAKAWA. You say you would not remove a ban on information?

Mr. KARCH. I believe that my advice to you in deciding whether or not to extend that ban is to try to take into account the full nature of the public interest at stake; there is a major public interest at stake here. I think also that in the history of the criteria used to evaluate cancer risks, and more recently to try to look at reproductive hazards and other kinds of hazards, there has been a very vigorous debate in the scientific community. In order for that kind of debate to happen, it has to be an open debate subject to very close scrutiny. I think that the limitation on access to the data covered by the proposed amendment would in fact be a significant limitation on debates on criteria for evaluating risks.

Now, I realize that there is a provision to try to make it available to scientists who would represent various groups. And here is where I will just take moment to describe some of the potential problems I see with the proposed changes.

First, I can imagine myself being asked to look at the data on behalf of an environmental group. In my work, I have worked for pesticide manufacturers, for the Government, and for public interest groups. But it would be hard to imagine not sharing it with a client because some of these data have great uncertainties and they are subject to multiple interpretations; it is very important to highlight assumptions made in the underlying analyses to a client.

I see that the way the provision is now written would restrict that kind of discussion.

Another problem is that risk assessment truly is interdisciplinary. In doing this kind of assessment, there is no one discipline that covers all aspects of the problem. Therefore, it requires the work of colleagues in various disciplines to analyze it. And I believe that the provision, the way it is now written, would restrict that.

Also, a lot of scientists, I suspect, would be uncomfortable because of the nature of the sanctions placed on releasing the data. Furthermore, I feel that the section is hard to understand. I am fairly familiar with the section, and I found it hard to follow in terms of what could be done and what could not.

The third problem I see is one that would be faced by EPA scientists, and this is how they would decide what constitutes a significant modification in innovative technology. I think because it is a difficult decision and because there would be a lot of pressure on EPA to grant 5 more years of confidentiality, I have the feeling that it is more likely that any modification would be extended for 5 more years. I believe it would be worth the attention of this committee in trying to provide guidance to EPA if this section is enacted.

Finally, I am concerned about a hypothetical situation arising that I think could be faced by someone in my position.

For example, if a consultant worked for Shell in 1978, but in 1982 was asked to look, on behalf of the Environmental Defense Fund, at data submitted by Dow, would this be a situation where Dow could challenge that because of the work in 1978 for a competitor? Could Dow challenge the scientist acting on behalf of the EDF the opportunity of getting ahold of that data? I think the section is somewhat open ended in this way, and I think EPA would benefit by guidance in this area.

Finally, this innovative methodology is an area where there is a lot of public funding, for example, radiolabeling is often cited as an example; in my thesis, I worked on isotope labels back in the late 1960's. It was funded by NIH.

Before that, the former Atomic Energy Commission funded a lot of research on radiolabeling of biological materials. So tracing the origins of such technology is a difficult thing because it is a combination of private and public funding. Here again there is a public interest and justification in keeping this data available.

Thank you.

Senator HAYAKAWA. Thank you very much, Dr. Karch.

Ms. Hinkle, I am sure that your organization has been involved with the use of DDT; is that correct?

Ms. HINKLE. Yes, Audubon and the Environmental Defense Fund, whom I worked for before, were the intervenors in the case.

Senator HAYAKAWA. If we look at the use of DDT, we see that the product is saving thousands of lives in Southeast Asia. And how would you balance this?

Ms. HINKLE. The public health uses of DDT were never contested. All public health uses were allowed even in the United States. The fact that DDT is not used, for instance, for malaria control, is because of resistance. It no longer works. And it has not been in use for several years now against malarial mosquitoes.

In other words, we supported the use of DDT for public health pests that caused diseases.

Senator HAYAKAWA. I see.

Mr. Lightstone, can you tell me specifically what remedies are currently available under Federal or State law to victims of pesticide misuse; that is, is there any State that you know of where an injured person cannot seek damages for his injuries in the State courts? And is it possible to get injunctive relief in State courts to prevent repeated misuse of harmful pesticides? And do States not have authority under FIFRA?

Mr. LIGHTSTONE. Senator, there are State court remedies, not against employers, usually because of workers compensation, but there are State court remedies of various types available for common law tort injuries. The difference in providing an employee right of action under FIFRA is that the the specific provisions of FIFRA are not those which one would be able to enforce in such actions directly. They would be evidence of a standard of care that defendant would owe to the plaintiff. By adding a private right in this bill, we would enable citizens to directly enforce the specific provisions of FIFRA without any question.

I might add through S. 2620 and your bill, S. 2621, there are various judicial remedies added for companies to sue other companies over these data issues, for example, with attorneys' fees and so on.

There are also common law tort remedies available to those companies under State laws to enforce unfair business practices and the stealing of trade secrets, but they feel it necessary to ask Congress to provide some specific remedies in FIFRA, and we feel we are entitled to the same kind of fair treatment.

And I might point out, for example, what I thought was a misleading statement this morning about litigation under S. 2621.

Mr. Engel in his testimony claimed that S. 2621 would not produce a great deal of litigation because only the States could sue the EPA if EPA vetoed a State data request. Well, that is a little bit misleading, because if you look on page 4, lines 11 through 15, of S. 2621, you will find that the applicant gets a choice; that is, the pesticide company can sue over a data request, sue the State directly in Federal court either before or after the Administrator has determined whether or not to veto a State data request.

In other words, pesticide companies can appeal a State data request under this bill to the EPA, and if the EPA says, no, the State is being reasonable in the State's request, the pesticide company can turn around and sue anyway in Federal court. That is unfair.

Senator HAYAKAWA. Thank you.

Mr. Feldman, I have a question for you.

Have you actually reviewed the University of Iowa studies that you referred to, that is, is there anything in that study that suggests that these cancers are connected with pesticide use?

My information is that the study does not make that connection.

Mr. FELDMAN. The study had a control group for smokers and nonsmokers, and what was controlled in effect were the smokers. So what we were left with in looking at that study, which appeared from 1971 to 1978, I believe, was a series of occupational hazards, a range of occupational hazards which included exposure to chemical pesticides. So that there is a clear correlation between occupational exposures, occupational hazards, and nonsmoking.

Senator HAYAKAWA. You mean it is real clear?

Mr. FELDMAN. That control group in terms of smoking versus nonsmoking is clear.

Senator HAYAKAWA. That was clear?

Mr. FELDMAN. Yes.

Senator HAYAKAWA. We can see that there was no linkage direct to the pesticides, it was just people in this occupation had slightly higher cancer rates——

Mr. FELDMAN. As I mentioned in my testimony, the scientific community is very divided on all the variables that in effect could or could not cause cancer. And this relates to the birth defects which were cited by the CDC. The cause of cancer most often cited is smoking. In this case, that control group was taken out, and as a result you are left with a series of occupational exposures which would lead us to believe that one should more closely look at pesticide exposure on the farm.

Senator HAYAKAWA. Thank you.

Now, this is when I promised I would go away, but I want to be totally fair. I want to give each of you the opportunity to make a one sentence statement of what is most important to you, starting with you, Ms. Hinkle, one sentence, now, not too long.

Ms. HINKLE. The most——

Senator HAYAKAWA. Important part of this testimony as far as you are concerned.

Ms. HINKLE. The change of one word from "a" to "any."

Senator HAYAKAWA. Change "a" to "any."

Ms. HINKLE. In section 6(b).

Mr. FELDMAN. I would hope what you would walk away from this testimony with, Mr. Chairman, is a sense that we are being presented here with a special interest bill; that we need to broaden the scope of that bill, and that in effect can be done within the next session of Congress, that you go ahead with the passage of the simple reauthorization which Mr. Helms has already entered—S. 2245—and that we can continue discussions on these issues which we have raised today and at a later date address a more comprehensive reauthorization.

Senator HAYAKAWA. Thank you.

Mr. LIGHTSTONE. Senator, the enactment of section 2621 or any of the changes that have been proposed in section 24 will undercut

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and effectively enable the industry to block the State effort to close the data gap——

Senator HAYAKAWA. Hold it, effectively institute what?

Mr. LIGHTSTONE. I think it will effectively enable the industry to block——

Senator HAYAKAWA. Enable the industry to block?

Mr. LIGHTSTONE. State efforts, the pesticide industry to block efforts to close the data gap and to gather crucial data that would be in the interest of growers and farmers and consumers to have produced and evaluated.

Senator HAYAKAWA. Now, you run into objections in that case of potentially many different sets of laws in different States, do you not?

Mr. LIGHTSTONE. At the present time we are talking about one State that has a very solidly grounded State program in terms of data requirements——

Senator HAYAKAWA. I know it is the State that was so successful in the Medfly.

Mr. LIGHTSTONE. You realize that the two are not really at all connected. Whether rat poisons are used in terms of what California can use for exposure data and metabolic data on these chemicals does not relate to agricultural spraying.

Senator HAYAKAWA. Dr. Karch, one sentence.

Dr. KARCH. The one thing I hope you would get out of what I have said is the importance of the public interest regarding this special provision to section——

Senator HAYAKAWA. Section 10?

Dr. KARCH [continuing]. Involving innovative methodologies and extending confidentiality to that type of data. As a matter of fact, I believe that the inert ingredients now listed for use in pesticide formulation, while inert for the purpose of killing the pest, are by no means inert when it comes to toxicity to workers and farm laborers. There is a strong public interest in not extending confidentiality to innovative technologies and in lifting the screen of confidentiality from inert ingredients.

Senator HAYAKAWA. Thank you very much.

I am very glad to have that question of inert.

Before I close this session of the hearing today, I would just like to mention that the hearing record will be kept open for 2 weeks to allow the submission of information such as any written questions of the staff or committee members may request the witnesses to respond to as well as the answers to relative material that may be submitted by all of you.

In addition, the committee has received extensive correspondence on this matter. And to the extent that it is appropriate, these letters will also be included in the overall record of these hearings.

Thank you all very much for your participation.

The hearing is adjourned.

[Whereupon, at 3:20 p.m., the committee adjourned, subject to call of the Chair.]

APPENDIX

STATEMENT OF HON. WALTER D. HUDDLESTON, A U.S. SENATOR FROM KENTUCKY

I wish to thank Chairman Helms for holding these hearings on proposed revisions of the Federal pesticide laws.

Congress has the duty to ensure that the Federal program that administers the pesticide regulatory effort runs smoothly and is equitable in its treatment of those affected by the program.

We must proceed carefully in developing legislation to revise the Federal pesticide laws. The Federal Pesticide, Fungicide, and Rodenticide Act and the legislative proposals involve complicated (and, in some cases, very technical) issues.

Beyond that, more importantly, the pesticide program must maintain a delicate balance between the need to protect the environment and the competing need to foster the development of pest controls on which public health and agriculture depend.

I am aware that the Federal pesticide regulatory effort, since the passage of the Federal Environmental Pesticide Control Act of 1972, has been plagued by controversy, delays and law suits. Congress must act, if possible, to resolve the problems surrounding this important program.

Therefore, I look forward to the testimony and recommendations for improving the program that we will receive today and tomorrow.

[Floor statement of Hon. S. I. Hayakawa, a U.S. Senator from California.]

[From the Congressional Record; Thursday, June 10, 1982]

Mr. HAYAKAWA. Mr. President, today I am introducing a bill to amend the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). My bill is designed to address a distressing problem that is beginning to surface all across our Nation. Quite simply, the problem is that States have been placing excessive and burdensome requirements on chemical companies in order to register pesticide products.

This is particularly a problem in California, our Nation's largest agricultural State, where the State Department of Food and Agriculture routinely requests data beyond that required by the U.S. Environmental Protection Agency before registering a pesticide. In fact, 85 percent of the applications for registration of products are required to submit additional data, data which the EPA has not seen fit to demand of registrants.

I wholly support the basic intent of FIFRA which recognizes the importance of protecting the health and safety of people and preventing the use of pesticides from adversely affecting the living environment. I believe that the initial passage of FIFRA was based on the congressional desire to bring some degree of national uniformity into the previously haphazard and often contradictory system of registration and application of pesticides in our Nation. California and six other States have attempted to expand their pesticide programs to exceed or duplicate the Federal registration requirements. If we are going to allow each State to establish its own registration process, to interject its own bias into that process, and to exceed or duplicate the entire EPA registration process, then maybe we should consider repealing FIFRA. This would save the taxpayers close to $100 million each year.

I do not think this would be a wise thing to do. But something must be done to limit the authority of States to undermine the integrity of the Federal pesticide registration process.

Allow me to reiterate my conviction that all pesticides, whether used nationally or centered within a particular State, must be safe and effective for their intended uses and that they do not pose unreasonable risks to man and his environment.

Both EPA and the States have an important role to play in insuring this result, but excessive, duplicative, and arbitrary regulation by the various States is certain to defeat this common purpose. Excessive State regulation imposes economic hardship upon the pesticide industry and deprives consumers within the 50 States of safe and effective pesticides needed to control pests which disrupt our economy and reduce the quality of our lives.

My bill sets reasonable standards for State regulation of pesticides to insure a proper balance between the role of the 50 States and the EPA. The bill is built around EPA oversight of the States' data requests when such requests are made based on a special local concern or upon a State's belief that additional data beyond that required by EPA should be generated.

This bill leaves intact the present State authority to regulate the sale or use of pesticides, but imposes the following standards for State review and requested generation of data:

First. In the case of existing data previously submitted to EPA in support of a Federal registration, the State may request the data from either the applicant or EPA, thereby resolving the current problem of data availability at the State level.

Second. In the case of special local concerns pertaining either to an increased risk or any unreasonable adverse effect on the environment or reduced efficacy of the pesticide within the State, the State may require additional data but must give the applicant written notice and justification for doing so. The State's request for special local concern data is subject to EPA review and subject to overruling or modification upon a finding that the State's request is arbitrary or capricious.

Third. A State's request for data which does not come within the realm of special local concern data is reviewable by EPA. EPA may disapprove a data request upon a finding by the Administrator that the request is "arbitrary or capricious or that there is no reasonable basis for making use of the data in connection with a State determination as to registration or approval of the pesticide."

Fourth. The State's decision that a special local concern exists and that additional data will be required before registration is granted is reviewable by EPA.

Fifth. The bill imposes an obligation on the States to act upon most registration applications within 60 days of receipt or the product is considered registered. However, it is different in the case of a pesticide utilized in the production of a commercial food crop. A change in the use pattern or a new active ingredient requires registration within 120 days after the receipt of the application.

Sixth. The bill clarifies the intent of Congress that FIFRA is designed to grant authority to no less than State levels of government. The possibility of fragmentation of responsibility within a State for pesticide use policies endangers the public health and safety by increasing the difficulty of the pesticides user community to know what rules apply at what time and to whom. Pesticide regulations at less than the State level of government will create confusion among users as to what is legal in the use of pesticides in the areas which they live or serve as businsessmen.

Detractors of my bill will claim that it is in conflict with States' rights. I have long respected and believed in the doctrine of States' rights. It is neither my desire nor my intent to dispute the rights of States to safeguard the health and safety of their citizenry. What concerns me though is excessive regulation, regulation which does not have a sound basis in scientific fact or regulations which establish barriers to interstate commerce. The California regulations for registration of pesticides are burdensome; they are not realistic and have negative long-term implications for the health of the State's agriculture. Let me remind my colleagues that this is not a California-only problem. The trend is being established; the fear of having 50 mini-EPA's is not that farfetched—preventative action is needed today.

Mr. President, allow me to take just a minute to discuss why Federal review of excessive data requirements is needed. Let me tell you some of the problems currently faced in California and of the consequences of unnecessary and unreasonable State regulations. I speak of California because of my familiarity with the situation there, but in many cases the problems are transferable. Surely the tendency of other States to follow the California lead is already surfacing. In California we grow over 250 crops commercially, many of these are specialty crops grown on limited acreage. The lengthy registration delays and excessive data requirements are making it increasingly difficult for chemical companies to justify the expenditure of resources required to obtain a registration. Manufacturers are effectively prevented from getting their products on the market in a timely and orderly manner. Consumers and users are often denied equal access to useful and effective pesticide products as a result of the deliberate barriers to registration erected by the State.

The California barriers to entry disrupt national distribution channels and nationwide advertising programs. Market access delays have cost individual companies hundreds of thousands of dollars and denied farmers the tools needed to compete in the national agricultural market.

Surely there will be opposition to my bill. The State of California will be loud and strong against it. They will claim that the problems have been solved, the backlog of registrations cleared and barriers to entry removed. I look forward to hearings when the chemical companies and farmers can tell us that in fact things are still a mess in California. I understand that the recent review of the State registration and use regulations has been productive. However, the fundamental bias of Governor Brown and his advisers against pesticide usage remains. I would like to share with my colleagues in the Senate two examples of the destructive and exploitative way in which the bias against economic poisons has been advanced by the Brown administration.

First, during the Mediterranean fruit fly crisis, the Governor initially refused to allow malathion to be applied from the air. This was done despite the fact that the safety and efficacy of the pesticide malathion are well documented. Governor Brown exploited the public's fear of the unknown; he used their ignorance to create a level of fear that bordered on hysteria. This was a cruel, unnecessary, and politically motivated manipulation of public concern.

The second example which I feel justifies the need for Federal review of State data requirements is contained in an internal memorandum to members of the Governor's toxic advisory group. This comprehensive new strategy for dealing with toxic chemicals in California contains two frightening proposals. First, the development of a carcinogen I.D. policy under which "The number of identified carcinogens will probably increase from 26 to several hundred." Second, the Brown toxics agenda includes "extension of workers right to know to consumers." This policy would provide for "labeling of fresh and canned produce and meat. Label will inform consumers of what carcinogens, neurological toxins and reproductive toxins are routinely applied to the commodity; what tolerance levels are set for each; whether or not monitoring techniques are available to detect them; and whether or not residues have been found."

The toxic substances agenda of California is devastating. I fear for the people of California who will be subjected to the patronizing and paranoid claims of the Brown administration. The public is being used, their emotions and fears are being played upon.

My bill will also raise opposition from the National Association of State Departments of Agriculture. This is difficult to understand given their awareness that a problem exists in California. Departments of Agriculture around the country will not be affected by this legislation as long as their registration process is timely and their requests for additional data do not fall into the category of "arbitrary and capricious."

Mr. President, before closing, I would like to list a few things that my bill does not do: It does not preempt the State's authority; it does not prohibit a State from banning a product or denying a registration; and it does not infringe on a State's right to ban or prohibit the sale or use but is directed solely to instances where the State requests additional data and to the timely processing of applications for State registration.

Thank you, Mr. President, for the opportunity to discuss the need for, and introduction of, this legislation on behalf of America's farmers.

STAFF SUMMARY OF S. 2621

The bill retains the current authority under section 24(a) of FIFRA for a State, but not a political subdivision of a State, to regulate the sale or use of any federally registered pesticide or device so long as it does not permit a sale or use prohibited by EPA. In addition, the bill includes new provisions regarding a State's authority to request health and safety data in regulating such sale or use.

Specifically, the bill authorizes a State, but not a political subdivision of a State, to obtain from EPA health and safety data previously submitted in support of the Federal registration of a pesticide.

With respect to special local concerns within the State, the bill—

(1) authorizes a State to require submission of additional data, but requires the State to give the applicant written notice of the purpose and justification of the request;

(2) provides that if an applicant wishes to contest a request for data involving a special local concern, the applicant may submit the request to the Administrator for review. If the Administrator determines that there is a Federal interest, the Admin-

istrator shall require the applicant to submit the additional data under the defensive data provisions of FIFRA. The Administrator may overrule or modify the State request for additional data if the Administrator determines that the request is arbitrary or capricious, or determines that there exist sources of comparable data that would be available to the State for the purposes of satisfying its request and so notifies the State. The State's determination that there is special local concern is also subject to review by the Administrator and to judicial review. The basis for any determination by the Administrator to modify or overrule a State's data request must be published in the Federal Register, and a State may obtain judicial review of any such decision by the Administrator. The applicant may seek judicial review of the determination of a State to require the data either before or after the matter has been submitted to the Administrator, but the Administrator would not be a party to any such action;

(3) requires a State, in connection with making a request for additional data, to consider the differences between various classes of pesticides regarding usage and environmental risk, and regarding the nature of the data appropriate to evaluate the risk for agriculutral versus nonagricultural pesticides; and

(4) provides that an applicant may advise a State of comparable data developed or being developed that will satsify the State's data request.

With respect to data that does not relate to special local concerns, the bill provides that requests by a State for any such data, not previously submitted to EPA in support of the Federal registration, would be reviewable by the Administrator. The request for data must be submitted to the applicant and a copy sent to the Administrator. If the Administrator determines that there is a Federal interest, the Administrator would require the applicant to submit the additional data under the defensive data provisions of the Act. The Administrator may disapprove the request if the Administrator determines that it is arbitrary or capricious, or that there is no reasonable basis for making use of the data in connection with a State determination regarding the registration or approval of the pesticide. If the Administrator has not taken any action within 60 days of the data request, or 15 days after receipt by the Administrator of any additional information that may be requested of the State, approval of the request by the State would be presumed. Any determination by the Administrator would be final and not subject to judicial review.

The bill also establishes time requirements applicable to the processing of applications for the registration of pesticides by the States as follows—

(1) except as to applications for which a State has requested health and safety data that relate to special local concerns, the bill requires a State to grant a registration, pending further review, if the State has not affirmatively approved or disapproved the application within (i) 60 days or such lesser period as provided in State law, or (ii) if the application for registration involves a restricted use pesticide, or a general use pesticide utilized in the production of a commercial food crop, and the use is a new use within a State, or the pesticide contains a new active ingredient, within 120 days or such lesser period as may be provided by State law after receipt of the application accompanied by the data or a citation to data required by State law at the time of application; and

(2) with respect to applications for which a State has requested health and safety data that relate to special local concerns, the bill authorizes a State to prohibit or restrict the sale or use of the pesticide or device pending development, submission, and review of the health and safety data.

The bill prohibits a State from restricting the sale or use of a pesticide or device for failure of the applicant to submit health and safety data requested by the State to the extent the Administrator has disapproved the request. In addition, the bill confers on the U.S. district courts jurisdiction to review determinations of the Administrator and the States (to the extent such determinations are subject to judicial review under these provisions), and to restrain violations of the time requirements provided for in the bill.

The bill further clarifies that, for the purposes of section 24 (authority of States to regulate the sale or use of federally registered pesticides) and section 26 (authority of States for primary enforcement of FIFRA violations) of FIFRA, the authority conferred on any State shall not be applicable to any political subdivisions or agencies of such State.

STATEMENT OF HON. ALAN CRANSTON, A U.S. SENATOR FROM CALIFORNIA

Mr. Chairman, I'm glad to have this opportunity to present my views on S. 2620 and S. 2621, legislation reauthorizing and amending the federal pesticide registration program under the Federal Insecticide, Fungicide and Rodenticide Act. Since I generally support the provisions of S. 2620, I would like to limit my comments to S. 2621 which would amend Section 24(a) of the Federal Insecticide Fungicide and Rodenticide Act to impose additional requirements in order for states to request information from chemical companies to review registrations. In effect, S. 2621 proposes to weaken seriously California's pesticide registration program.

California has had a pesticide registration program in operation for many years, predating the Federal Insecticide, Fungicide and Rodenticide Act. The state's experience has shown that local climatic conditions, local use situations, and the desires and needs of local citizens should be considered in determining which pesticides should be registered and how long they should be used in specific locales. The Federal government can't possibly deal with the vast diversity of needs and conditions in each state.

Under current law, federal pesticide standards are considered minimum standards and Section 24(a) gives individual states the authority to augment the standards set by the Environmental Protection Agency when necessary. California has exercised this authority to review the data required by EPA on pesticide chemicals and has requested additional data where necessary and imposed additional regulations and restrictions when needed to meet California's unique environmental conditions and to insure the health and safety of the people of the state.

S. 2621, however, would require the state to get approval from EPA in order to seek the additional information from the chemical company. If EPA—which has already registered the chemical—denies the state's request, the state would nonetheless be required under this legislation to register the federally registered pesticide without having a chance to evaluate pesticide use and toxicity data independently. In limiting the additional health and safety data requests by the states, S. 2621 undercuts the right of California and other states to establish pesticide programs tailored to local conditions and set stricter requirements than the federal government.

I would like to call to your attention several examples where the state's ability to review pesticide use and toxicity data have resulted in additional regulations and restrictions above those required by the federal government, providing clear health and safety benefits to pesticide users as well as to fish and wildlife. I would also like to note that California has taken action well ahead of the federal government to cancel registrations of chemicals subsequently found by EPA to pose unacceptable public health and safety risks.

For example California restricted, then phased out most uses of DDD and DDT in the late 1960's because of residue problems and environmental persistence. EPA did not cancel these chemicals until 1972. Again with DBCP, the state of California acted first—suspending registration in 1977 when problems of infertility of manufacturing plant workers and California applicators were discovered. Subsequently the state discovered that DBCP presented a groundwater contamination problem as well. The federal government suspended DBCP three years later, with the action based almost entirely on California's findings.

In the case of the pesticide guthion, California's review has resulted in protecting the public's health. California at first accepted the manufacturer's residue data on guthion that was reviewed by EPA for use on alfalfa. However, under California spring climate conditions, residues persisted on hay, posing a threat to consumers of milk from cows that ate the hay. The problem was spotted under California's surveillance system and additional data was requested from the manufacturing company. Use of guthion was phased out by the state, but EPA permits its continuation elsewhere. California also initially registered disyston for use on alfalfa, accepting the federally reviewed residue data. Shortly thereafter the state found that many cows became sick and died after eating alfalfa treated with disyston. By examining the data made available from the manufacturing company, the state determined that the data had not been evaluated by EPA for California conditions and that highly toxic breakdown ingredients had been overlooked. The state immediately stopped all use of disyston on alfalfa to prevent further deaths of cattle and the possibility of residues entering the milk supply. EPA has not taken action in other states and several million dollars of loss have occurred with cattle deaths.

Data required by EPA for registering the pesticide Torak also proved inadequate for California conditions. The state discontinued the use of the pesticide five years ago following the severe poisoning of 150 grapepickers who re-entered the vineyards that had been treated with Torak. EPA does not request or review toxicity data to determine pesticide persistence with respect to the health and safety of workers reentering the fields. Thus Torak remains registered for use in other states where EPA has not acted.

More recently, California reviewed Du-ter, a fungicide registered by EPA for use on rice. California's review of additional data it obtained from the manufacturer determined that Du-ter had an extremely teratogenic potential. As a result the state rejected the manufacturing company's request to register the chemical for use on rice in California. All other users of Du-ter in California have been put into the state re-evaluation process. Without the ability of the state to request additional data from the chemical companies, perform its own review and make independent conclusions, this highly toxic chemical might be in use on California's rice crop today as it is in other states, threatening the public's health.

Furadan, an insecticide used on grapes, formerly was applied in granule form to grapes in California without further augmentation of the treatment process. Data from this pesticide use indicated that birds were being poisoned as a result of either directly consuming the granules or indirectly drinking water in the fields contaminated by the granules. Recommendations by the state resulted in further restrictions on the material which required it to be incorporated into the soil immediately after application. These additional restrictions listed on the state label halted further bird losses in vineyards.

Another example of California officials augmenting restrictions on the use of a federal registered pesticide is with the use of Azodrin on cotton fields. Several years ago in California's San Joaquin Valley, pheasants were dying in cotton fields that had been treated with Azodrin. The state discovered that pheasants were using cotton fields for cover after July 15 and drinking irrigation water that had been contaminated with Azodrin. As a result of these discoveries, the state determined that Azodrin should not be applied to cotton fields after July 15 and this restriction was placed on the state Azodrin label. By responding to California's unique conditions, pheasant losses have stopped entirely.

These are just a few examples of California's need to require pesticide data beyond the studies that EPA requires. The proposed amendment to Section 24(a) of the Federal Insecticide, Fungicide and Rodenticide Act would effectively pre-empt and restrict the state from managing pesticide use in the diverse and unique environment of California. I strongly believe that California should be able to maintain its ability to make appropriate risk assessments on pesticide use to ensure public health and safety and adequately protect fish and wildlife in the state.

I know there has been some criticism of the California pesticide registration in the past because of delays in processing chemical registration applications. When the Federal Insecticide, Fungicide and Rodenticide Act first went into effect there were in fact backlogs. However, this backlog of applications has now been eliminated and chemical companies should be accustomed to the requirements of the state for pesticide data. It's my understanding that California now receives about 100 applications a month, many for new uses of products already on the market and registered with the state. For such applications, the processing often takes no longer than three days. I would also like to note that in the twenty years of California's administration of its pesticide registration program there has been only one lawsuit brought because of a processing delay. There just is no basis at this time for the charge that the state program causes undue delays in registration or that requests for additional information are arbitrary or capricious.

Mr. Chairman, the Reagan Administration has argued forcefully for transferring responsibility for programs to the states. The State of California has the personnel and program in place to administer the pesticide program in a way that meets the state's needs, which given the funding and personnel limitations of EPA is well beyond the agency's capability. I urge the Senate Agriculture Committee to reject this attack on the state's rights and defeat S. 2621 as it moves forward with S. 2620 to reauthorize the Federal Insecticide, Fungicide and Rodenticide Act.

STATEMENT OF
DR. JACK D. EARLY, PRESIDENT
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
UNITED STATES SENATE
JUNE 21, 1982

Mr. Chairman, I am Jack D. Early, President of the National Agricultural Chemicals Association (NACA). The National Agricultural Chemicals Association is a non-profit trade organization of manufacturers and formulators of pest control products employed in agricultural production. NACA's membership is composed of the companies which produce and sell virtually all of the technical crop protection materials (active ingredients) and a large percentage of the formulated products registered for use in the United States.

NACA supports the passage of S.2620 and would like to commend you, Mr. Chairman, for introducing a bill that has addressed the concerns of our industry and of other concerned groups in a balanced way. Although this bill is basically similar to the bill reported by the House Agriculture Committee, it makes a number of constructive changes and improvements which I believe are important to our industry and to the agricultural community.

Essentially, this bill represents several compromises worked out between all segments of the pesticide industry, the agricultural community, user groups, environmentalists, labor organizations and the Environmental Protection Agency. No one group has been able to obtain all of the changes it wanted, and certainly there are many ways in which NACA would like to change this bill to meet all of the desires of our members. But in the end, the important fact is that this bill reflects a workable compromise -- a compromise that accommodates every group's principal and legitimate concerns, and a compromise that our industry is satisfied with.

Need for Protection of Research Data

The principal concern of NACA in this legislation is to preserve the economic incentives for the agricultural chemical industry to invest in research and development. These incentives are maintained by providing proprietary protection for innovative research data and scientific information generated by a company and submitted to the Environmental Protection Agency in support of pesticide registrations.

Our agricultural production and enterprise is one of the greatest resources that we have in this country. Today, less than three percent of the U.S. population feeds this country as well as much of the rest of the world. In 1980, exports of agricultural products contributed almost $40 billion to our balance of payments.

The use of agricultural chemicals has permitted us to enjoy this position of world preeminence in food production. Agricultural chemicals significantly reduce the losses of food to pests, increase farmers' crop yields and profits, and lower agricultural production costs. They improve food quality by reducing contamination and pest-induced toxins. And these chemicals also reduce the risk of human disease caused by insect pests, rodents, bacteria, and the like.

Innovative research and development of newer, safer and more effective products and uses is perhaps the most important factor behind this country's success in the field of food production. Innovative research, however, must be supported by realistic economic incentives. To accomplish this, the fruits of this research -- the scientific data and information concerning the efficacy, safety and properties of a pesticide -- must be given protection from commercial exploitation by competitors.

The competitive threat to our innovative pesticide producers is very real. Virtually every country in the world has an interest in agriculture and to varying degrees in the use of agriculture chemical products. Foreign and multinational corporations stand ready to exploit the research efforts of our innovative companies to compete with them in world-wide markets. It is critical to the funding of this high-risk, expensive research that innovative companies be able to reap the benefits of their research investment.

On the average, 10,000 to 15,000 chemicals must be synthesized and screened in order to identify one commercial product. Performing such research, however, is by no means a guarantee that a new successful chemical will be identified. Even when a potential new product is found, it must undergo several more years of expensive testing without any guarantee that it will be approved for registration by the Environmental Protection Agency, that it will be accepted by the agricultural community, that it can be profitably manufactured, or that it will be successful in competition with other products. In short, such research is a very high-risk venture.

The cost of innovative research is substantial. It now takes approximately $20 million to $25 million on the average to bring a new product from discovery through registration. The time from discovery of pesticidal properties of a compound to commercialization is nearly eight years, according to 1979 statistics. This is an increase of more than 60 percent since 1967 in the time required to commercialize a product.

When a new product is successfully developed, the research data that demonstrate the chemical's efficacy, safety and properties become a valuable commercial commodity. These data represent the key to obtaining market approval for a new chemical or a new use both by the United States Environmental Protection Agency and by governmental agencies in other countries. If competitors were permitted to use these data for their own commercial purposes, without having to make the same multi-million dollar investment, without having to take any risk of loss, and without having to experience the eight-year marketing delay suffered by the data developer, there would be little or no incentive for companies to invest in innovative research.

While patents help to provide some protection for innovative companies, patent protection by itself is insufficient to prevent competitive injury to the data developer. Patents afford no protection for innovative scientific research and test data generated by a producer and submitted in support of an EPA registration. Moreover, some companies attempt to avoid patents by making slight alterations to the chemical structure of a compound. In this situation, a patent affords no comfort to an innovative data developer.

More than one-third of the patent life for a new compound may be lost because of the time required to test the product, gain registration approval by EPA, and bring the product to the market. Research to develop new uses on older chemicals for which patent protection has expired would be completely open to competitive exploitation unless the research data are provided protection under FIFRA.

Finally, patents offer no protection against the use of research data disclosed under FIFRA to obtain registrations in foreign countries.

The potential use of data disclosed under FIFRA for foreign registration purposes is a matter of great concern. Until recently, litigation concerning the FIFRA disclosure provisions has prevented the release of most competitively valuable scientific information. In many cases, agreements have been reached between data submitters and public interest-type organizations that have requested access to health and safety data for the purpose of conducting a peer review. Such voluntary agreements have permitted access to the data under conditions that ensure they will be safeguarded and will not be released to competitive businesses.

Nevertheless, we are aware of an incident that arose only in the last few weeks, in which Monsanto Agriculture Products Company has charged that EPA has released scientific information proprietary to Monsanto concerning one of its most important products to a Washington, DC law firm believed to be acting on behalf of a competitor. The current FIFRA provisions unfortunately do not contain sufficient safeguards to assure that the disclosure of valuable research data to competitors will not be permitted.

Although section 10 of FIFRA as amended in 1978 serves the legitimate purpose of permitting public interest-type organizations and scientists to review health and safety information submitted by registrants, it does not make sufficient distinctions between persons acting in the public interest and persons acting on behalf of competitors seeking to exploit these valuable data for their own commercial gain. There are simply no adequate controls under the current FIFRA or EPA regulations to prevent competitors from gaining access to this scientific information.

Once data were obtained by a competitor under FIRRA, they could be used in numerous countries, such as Canada, France, Germany, Czechoslovakia and Japan, for the purpose of gaining market approval. We are aware of no foreign government that would inquire as to whether the data were obtained from EPA with the data developer's permission, or that would prohibit the use of such data in that country if they had been obtained without the data developer's permission. In most countries of the world, the fact that data are obtained from EPA would lend greater credibility to the information for purposes of gaining market approval.

The result would be that a competitor who obtained another company's research data from EPA would receive a free multimillion dollar ride. The competitor could enter the foreign markets without having risked a $20 million to $25 million investment and without having had its market entry delayed for eight years without profit while the testing was being performed and the application for market approval was pending. This type of disclosure would inflict direct competitive injury on the innovative research-oriented companies in our industry.

In addition to this direct competitive harm, equally serious is the use of these research data for increasing the technological base of competitors. To permit such use would substantially weaken the United States as a world leader by allowing our technology to be exported free of cost to foreign countries. Many of the innovative basic pesticide manufacturers have developed scientific methodologies and techniques in their research that are used to discover and develop new products. The development of such innovative methods represents an important and expensive part of the research effort. Some companies for example have developed techniques of radiosynthesis used in their research that are believed to be unique. Certain portions of the information in residue chemistry and metabolism studies provide a source of leads for the discovery of new, more effective and safer agricultural chemicals.

If these types of data were disclosed to competitors, the innovative companies who developed them at great cost and effort would experience substantial competitive injury. We believe that this type of unrestricted disclosure of scientific information under FIFRA would stifle the development of U.S. technology. It would serve as a disincentive to research of new agricultural chemicals which could be safer to humans and the environment and which could increase the productivity of U.S. agriculture.

We believe that technology grows only in those countries that provide an environment where an innovative researcher can be rewarded for his efforts. The net result of unrestricted disclosure of scientific data under FIFRA could be to force innovative research and product development out of the United States and into countries such as Japan where the value of protecting proprietary scientific information is clearly recognized.

Our concern over the disclosure of research data reaches not only the problem of releasing such information to competitors but also to the problem of the release of data to certain foreign governments. Eastern bloc nations in particular have used every means at their disposal to obtain and exploit U.S. technology and have not let obstacles such as patent protection stand in their way. In these countries, government-affiliated companies are in direct competition with innovative members of our own industry. To preserve the preeminence of the United States in the field of agricultural chemical technology, research data should not be disclosed to these foreign governments unless the data owner is satisfied that the government in question will adequately safeguard the information from competitors.

Section-by-Section Analysis of S.2620

Use of Data Provisions

The "use of data" provisions of S.2620, which would be incorporated in section 3(h) of FIFRA, provide important proprietary protection for research data that will enhance the incentives to invest in innovative research programs. This section provides that for a period of 15 years, data submitted to support the registration of a new chemical or of a new use may not be relied on by any other company without the permission of the data owner.

Under current law the period of proprietary protection for data concerning a new chemical is limited to 10 years. The bill reported by the House Agriculture Committee, H.R.5203, increases the period of proprietary protection from 10 years to 15 years. The period of protection actually begins on the date that data are first submitted in support of a registration, including data submitted in support of an experimental-use permit, and extends for 15 years from the date of the first approval of the registration for that active ingredient.

Although H.R.5203 provides a 15-year period of protection for data submitted to register new uses for both old and new chemicals, this protection would apply only in the case of a major change in use pattern for a product. S.2620 improves the economic incentives for investing in research to expand uses by granting a 15-year period of protection for any data required by EPA for the registration of a new (not previously registered) use. These provisions ensure a reasonable degree of protection for companies investing in scientific research on agricultural chemicals. We believe they will stimulate the discovery of new crop protection products that are more effective and economical, and safer to humans and the environment. They will also encourage research to register minor uses and to satisfy specialty crop pest control needs.

Section 3(h), as worked out in compromises between all members of the pesticide industry and the Environmental Protection Agency, would require every applicant to independently submit to EPA the "data required for registration" of the applicant's product. If data were protected under the exclusive-use provisions of the bill, they could be used by another applicant only with the permission of the data owner.

Research-oriented manufacturers who have introduced new and innovative products to the market through their research efforts often will recoup their investment by selling a manufacturing use product to another company for formulation in to an end-use product. In order to ensure that a competing manufacturer cannot obtain an identical "me-too" manufacturing-use registration without submitting the same kinds of expensive research data generated by the original registrant, section 3(h) delineates the kinds of "data required for registration" by these subsequent applicants. It provides that they must submit all of the same types of expensive research studies that were required of the original registrant, including both the data concerning the manufacturing-use product and the data concerning the end-use product (except for acute toxicology data or similar data that pertain only to a specific formulation). The data required of the "me-too" applicant would include all of the chronic and subchronic studies, residue data, animal and plant metabolism data, environmental fate data, data concerning safety to domestic animals, fish and wildlife, non-target organisms, etc., regardless of whether the "me-too" applicant is registering a manufacturing-use or end-use product.

It is only by requiring that "me-too" registrants submit the same types of expensive studies required of the original registrant that the data protection provisions of section 3 (h) have meaning. It is NACA's understanding that the compromises developed under section 3 were intended to be construed in this manner and will be so interpreted by EPA. Furthermore, we understand that the fact that data may have been required to be submitted to obtain a tolerance for a chemical would not diminish in any respect their proprietary protection under FIFRA. Because a tolerance is required for registration under FIFRA in the case of agricultural products, data submitted to obtain the tolerance also are intended to be "data required for registration" under FIFRA within the meaning of section 3(h). Similarly, if the original registrant has submitted data to establish a tolerance for particular crops within an EPA crop grouping, "me-too" applicants also would be required to submit the same data in order to obtain registrations for those crops.

Cite-All Amendment

S.2620 confirms the original intent of the 1978 FIFRA amendments by providing that an applicant for registration has the right to choose the method of supporting his registration. The applicant may obtain a registration by relying entirely on data that he has generated and submitted, or by citing and relying on data submitted by other applicants that are available for his use under the terms of the "use of data" provisions of the Act. This amendment makes clear the original intent of Congress in 1978 that EPA may not abridge the right of an applicant to rely solely on its own data for registration purposes without citing or paying compensation for data submitted by others.

Additional Data to Support Existing Registrations

Like H.R.5203, S.2620 amends section 3(c)(2)(B) of FIFRA to provide a more equitable system for sharing the cost of developing additional data requested by EPA. If a registrant fails to enter into a joint data development arrangement with the other registrants, or fails to take appropriate steps to secure and submit the data required by EPA, his registration must be suspended. S.2620 also makes EPA responsible for ensuring that registrants comply with the terms of a joint data development arrangement. This arrangement will provide for more effective compliance than under the House Agriculture Committee bill, which permitted a registrant to enforce a data development contract through a federal court lawsuit.

S.2620 also makes it clear that a subsequent applicant who was not part of a joint data development arrangement but who wishes to rely on the data submitted by joint data developers must pay a share of the "inflated" or "real" cost of producing the data as of the date of his application.

Finally, S.2620 also improves upon the terms under which registrants may gain entry into existing data development projects initiated between September 30, 1978 and the date of enactment of the 1982 FIFRA amendments. Where such data currently is being developed by a group of registrants under an existing agreement, a new registrant wishing to join the group must adhere to whatever cost-sharing terms are provided in the existing agreement. In other cases, where for example data are being developed by a single registrant, another person wishing to participate in the development of such data must agree to share in the cost of the data on a pro rata basis (i.e., in proportion to the total number of persons participating in the joint data development).

Formulator Exemption

S.2620 makes a number of amendments to the formulator exemption in section 3(c)(2)(D) which retain the concept of the formulator exemption under existing law, but provide more effective means for protecting the rights of data owners.

In order to protect new use data, this section provides that a formulator must obtain the permission of the owner of new use data entitled to exclusive-use protection in order to obtain the benefit of the exemption. The exemption would apply only as long as the conditions of the authorization to rely on the new-use data remain satisfied.

In addition, if a formulator at any time ceases to use a purchased registered pesticide as the source of the active ingredient in his end-use product, the formulator exemption would no longer apply.

If the formulator exemption ceases to apply under either of these two new provisions, and the formulator does not agree to supply the data required for registration, the formulator's registration would be suspended.

These changes will ensure that formulators who legitimately are entitled to the exemption will continue to receive the benefit of it, and at the same time will enable a data submitter to recoup his research and development expenses by granting permission to rely on his data to formulators who purchase his products.

Data Disclosure Provisions

S.2620 amends section 10 by providing significant controls on the disclosure, copying and transfer of research data in order to prevent the release of this information to pesticide producers and registrants who are in competition with the data owner. At the same time, this section continues to permit members of the public who have no competitive or commercial interest in the production or registration of pesticides to review health and safety information. The controls on copying and transfer of data are designed to safeguard the data from competitors, not to restrict access by non-competitors.

Under this provision, the general procedures for the release of data are revised to ensure that data submitters will be provided with a reasonable period of time, up to 60 days, in which to review data for the purpose of identifying portions that are trade secret, confidential, or contain innovative scientific methods. A data owner must be provided with an additional 30 days notice prior to the initial public release of information claimed to be protected so that he may take steps to seek court review if necessary.

EPA is required to promulgate regulations under this section providing procedures for granting access to health and safety data, and prescribing conditions governing further copying or transfer of data, and for safeguarding of data. These regulations will give data owners an opportunity to confirm that persons who receive data from EPA are not affiliated with another pesticide producer or registrant, and will enable the data owner to keep a record of the number and location of copies of data that are in circulation.

This section prohibits EPA from disclosing information of a data submitter to any pesticide producer or registrant, to persons outside of the United States, or to foreign nationals who would remove the data from the United States.

Innovative scientific methods and technology are provided a further degree of protection in that they may generally be made available to scientists seeking to conduct a peer review of data but would not otherwise be given public distribution. This will enable data to be given full independent scientific scrutiny without releasing valuable innovative methods to persons with competitive interests.

Severe penalties are contained in the bill for persons who violate the disclosure provisions in furtherance of a commercial purpose involving the production, registration, distribution or sale of a pesticide. These penalties include the mandatory cancellation of all registrations issued to a violator and to anyone on whose behalf the violator was acting. These penalty provisions will help to preserve the competitive value of research data submitted to EPA.

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Washington, D.C., July 21, 1982.

Re Amendments to the Federal Insecticide, Fungicide, and Rodenticide Act.

Senator JESSE HELMS,
Chairman, Senate Committee on Agriculture, Nutrition and Forestry, Russell Senate Office Building, Washington, D.C.

DEAR SENATOR HELMS: The National Agricultural Chemicals Association testified before the Senate Committee on Agriculture, Nutrition and Forestry on June 21, 1982 in support of the amendment contained in S. 2620 that would prevent the disclosure to competitors of innovative scientific methods and technology that are developed and employed in agricultural chemical research. In response to questions raised at those hearings we offer the following paper to better define the types of information that would be subject to protection as innovative methods.

Sincerely,

JACK D. EARLY.

Enclosures.

INNOVATIVE METHODS AND TECHNOLOGY

In the course of performing chemistry research to determine the nature and amounts of parent and breakdown products in plants, animals and the soil, innovative companies may develop new scientific techniques and approaches. The development of new techniques usually requires a substantial investment of manpower, money and time. If successful, these techniques will enable a company to solve previously insoluble research problems, or to perform research tasks more accurately and at lower cost than known methods would permit—or than competitors could accomplish. Such innovative scientific methods and technology consequently provide the pioneer company with a competitive edge and traditionally have been considered trade secrets. Because several companies often will develop competitive products that have similar chemical structures or physical properties, new scientific techniques developed by a pioneer company could have great competitive value to other members of the industry. Examples of such methods and technology would include the following:

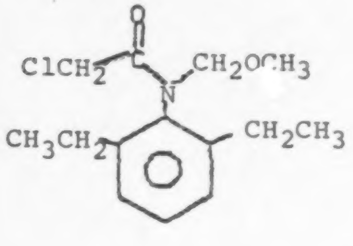
1. In order to help identify and measure extremely low levels of metabolites of pesticides in plants and animals, the Monsanto Company spent several years in the development of a scientific technique for using the Carbon-13 (^{13}C) isotope. This technique enabled Monsanto to take the very low level measurement it needed, to do so more accurately and two to three times more quickly than could be done by previously known methods, and to identify many more metabolites. This innovative technique could have been used in a variety of applications of chemical research, and at the time would have been very valuable to competitors if released by EPA. This method was maintained in confidence by Monsanto for approximately eight years and was published by the company in 1977.

2. In order to identify trace levels of chemical breakdown products in the environment, and to measure their presence at very low levels, a member company developed novel high-pressure liquid chromatography instrumentation. Because existing technology would not permit the company to obtain the environmental chemistry data it needed at the very low levels being studied, it had to develop a new scientific system and approach. This instrumentation would have been valuable to competitors working with chemicals that have similar properties. Release of this information thus would have erased the competitive advantage that the company earned through its expensive research efforts.

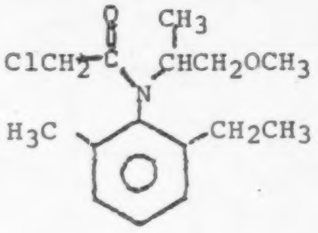
3. Because fewer than 1 in 15,000 chemicals that are synthesized in research actually will possess the properties necessary and meet all of the requirements for a commercially successful agricultural chemical, competitors often attempt to introduce slight variations to the chemical structure of a known successful product in order to develop a similar if not improved chemical and one that will not violate the patent for the original compound. The structure of certain metabolites of a commercially successful compound, and the biological "pathways" of such chemicals in plants and animals, can provide valuable information that could be used for exploratory synthesis of new pesticidal molecules, biological crop antidotes, crop safeners, and compounds having more biologically selective effects. This information in chemistry and metabolism studies could have enormous value for product development purposes if released to competitors.

The commercial value of innovative methods and technology to a competitor is even more apparent when one observes the many competitive products with similar chemistry for which such scientific techniques would have ready application. Compare for example the following chemically similar commercial products:

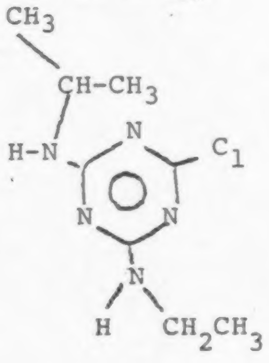
Alachlor
(Monsanto)


O
ClCH2
C
N
CH2OCH3
CH3CH2
CH2CH3

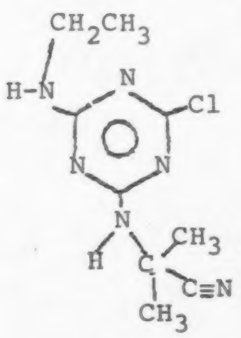
Metolachlor
(Ciba-Geigy)


O
CH3
ClCH2
C
N
CHCH2OCH3
H3C
CH2CH3

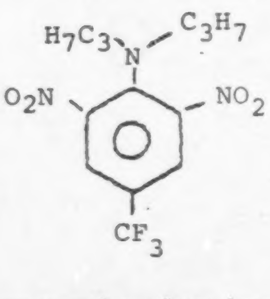
Atrazine
(Ciba-Geigy)


CH3
CH-CH3
H-N
N
Cl
N
N
N
H
CH2CH3

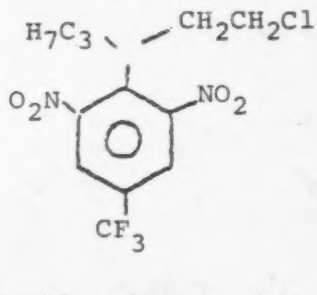
Cyanazine
(Shell)


CH2CH3
H-N
N
Cl
N
N
N
H
C
CH3
C≡N
CH3

Trifluralin
(Eli Lilly)


H7C3
N
C3H7
O2N
NO2
CF3

Fluchloralin
(BASF-Wyandotte)


H7C3
CH2CH2Cl
O2N
NO2
CF3

In cases such as these, innovative methodologies developed by a pioneer company could be appropriated by another company for research on a competitive product.

These kinds of innovative methods and technology cannot effectively be protected by the U.S. patent laws. Such methodologies and technologies rarely are patentable. Even if they are patentable, the patent typically could not be enforced because of the difficulty in detecting use of the methods by others and proving infringement.

Thus the limited restrictions on the disclosure of this narrow category of information contained in S. 2620 and H.R. 5203 provided the only effective means of preventing the commercial exploitation of extremely valuable proprietary scientific methods and technology developed in chemistry research on pesticide products. This legislation would proscribe the publication of innovative methodology for five years but would immediately permit scientists acting in the public interest to have full review of such information. NACA believes that the justification for the protection for innovative methods and technology has been amply supported and urges the adoption of this provision.

Prepared Statement of
JOHN M. WISE, President
Pesticide Producers Association
Washington, D.C.

before the

U.S. SENATE AGRICULTURE COMMITTEE

on S. 2620 and S. 2621, Federal Insecticide,
Fungicide and Rodenticide Act Amendments of 1982

June 21, 1982

USE INCONSISTENT WITH THE LABELING, SECTION 2ee

The State of the Art of a Formulation is not mysterious alchemy nor it is based on any form of magic. It is based completely upon scientific knowledge backed by years of research. The small producer/formulator plays an integral role, usually as a regional or local supplier to the Agricultural Community. This producer supplies his local area with pesticides designed specifically for that area and usually also distributes pesticides from other manufacturers.

In order to play this important role in the agricultural cycle, the small formulator/producer must be allowed to use all the essential tools that he can obtain to be competitive and still supply his community with quality products. New Section 2ee will allow the small producer/formulator to continue a standard practice that has historically been used since the era of modern Agricultural Chemicals as an industry began -- the ability of being able to utilize a registered end use product to reformulate or repackage into another registered end use product.

The small formulator/producer, in order to supply the variety of products necessary for local needs, cannot afford to purchase large volumes of technical pesticides for formulation. Instead, he (the formulator) can use a registered concentrated end use product and reformulate into a product for local need. Equally, he cannot afford to purchase large quantities to sell quarts and pints for local consumption, but can economically repackage into smaller units as needed by the local populace.

We respectively urge your support for this portion of the amended FIFRA.

FORMULATORS EXEMPTION, SECTION 3(C)(2)(D)

FIFRA SECTION 3(C)(2)(D) is presently Formulators Exemption. It is the belief of the Pesticide Producers Association that this exemption should not only be continued, but strengthened.

It is a fact that overregulation profits no one, but the large and powerful companies and is probably the largest problem the small company has today. Small companies are unable to bear the massive costs of regulation. They have neither the staff to handle compliance nor the volume and production to spread out the increased capital and operating outlays.

This is also true of data production. A small formulator may have between 50 and 200 end use labels for formulations he produces or resells. Each labeled product may only generate a small amount of his income, but all are important to the eventual profitability of this company.

The cost to produce the data necessary to maintain these formulation labels is between $10,000 and $20,000 per label. For an average of 100 labels, the cost would be between one and two million dollars. Very few small companies can afford to continue operating with an overhead as high as this, caused by regulation. We believe that a statement by Rep. Floyd Fithian, June 16, 1981, best expresses the plight of the small producer --

> "Let me get to another question that I think we have to deal with here. There is the question of whether or not you deal with market share as a method of determining preparation of data and defensive data or whether we continue under the system we use now.
>
> Mr. Emerson, one of the areas in which industry has not come to an agreement among themselves is how to compensate back and forth. This deals with the question of either market share or does everybody share equally.
>
> I believe before you came in somebody gave an example of a company with a relatively small part of the market share taking a look at a $300,000 up front money and saying they would not get into that.
>
> Let me share a little bit of concern I have about the whole law. Maybe I am wrong. I get the notion that we have the regulatory system -- and this is not just in FIFRA -- in this country so hidebound that we are quickly developing to the point, unintentionally, where only the very, very largest companies are going to be able to survive at all.
>
> We are basically going to eliminate the smaller companies across the board.
>
> I think the criticism which we have received on this Committee is that unintentionally what we are doing is by law developing in such a way that the large will get considerably larger and we will eliminate essentially the medium and smaller companies in the industry.
>
> I do not know whether this particular program of compensation that we are talking about this morning might contribute to that. I think we are under a lot of criticism as a committee because we have seen a pretty rapid evolution of larger and larger and fewer and fewer industries in the pesticide business.
>
> Those who set out to regulate pesticides in the first place just as those who set out to regulate other kinds of drugs in the Food and Drug Administration, or other products in society did not really mean to use the regulatory arm of the U.S. Government to destroy competition.
>
> But effectively it is destroying competition. Would the panel comment on that. Maybe the criticism I am getting is unjustified, but that is what I am hearing."

The FIFRA Amendments go a long way to alleviate the formulators' problems. It will help to keep the small and medium sized companies in business and keep competition in the marketplace. We urge your support of this amendment.

REGISTRATION OF PESTICIDES, SECTION 3.

Since the passing of the amended FIFRA in 1972, there has been a constant disheaval of the pesticide manufacturing and formulating industry within the United States due to certain provisions of Section 3 revolving around --

(1) Data compensation and the use of data by the Administrator for registering pesticides.
(2) The need of the Administrator for additional data to update his files to bring old pesticide registrations into compliance with the new law.
(3) The need for a simplified procedure for registering pesticides which have previously been registered by the agency, often referred to as "me too" registrations.

The Pesticide Producers Association has reviewed this section and is proposing changes in Section 3(c)(1)(D), Section 3(c)(2)(B) and Section 3(c)(2)(C) to correct these problems.

Section 3(c)(1)(D)

The amendments being proposed by the Pesticide Producers Association will do away with data compensation by 1993, while at the same time allowing for an incentive to the producers of data to go forward in development of new uses and new pesticide products.

Section 3(c)(1)(D) has proven to be totally unworkable both from EPA's, basic producers' and the formulators' point of view. This was recognized by EPA as a possible problem in a report written in 1976 which states that the results of Section 3(c)(1)(D) could force formulators to drop products, force certain formulators out of business, and could result in a reduction of competition in the industry.* At that time no data compensation hearings or claims had been processed through the administrative process. In 1980 the first decision from the Administrator on a 3(c)(1)(D) data compensation claim was issued by Administrative Law Judge Gerald Harwood. The case, Ciba-Geigy Corporation versus Farmland Industries, involved over two years of case preparation and expense of over one million dollars in legal fees for a data compensation settlement of less than $250,000. This case was the first and has been viewed as a landmark case in the area of data compensation. The decision was appealed in district courts and more legal fees were amassed, legal fees which could be spent for research.

Although this case was heard under the 1972 amendments to FIFRA, the 1978 amendments would in no way lessen the overall expenses to have carried this data compensation claim through the Administrative process. The 1978 amendments to FIFRA provided for an arbitrator rather than an administrative law judge, and the expenses of the arbitrator would have been divided between the two participants in this case while the government bore the cost of the administrative law judge. Therefore, the 1978 amendments would have only increased the cost of this hearing rather than provided for a less expensive and more expeditious process.

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* Incremental Cost Impacts of the 1972 Federal Insecticide Fungicide and Rodenticide Act as amended; January 1976; EPA-540/9-76-002, Pages 42-43.

If the above case had not involved two large corporations but instead, a large corporation and a small formulator, the formulator would have been forced either out of business or to remove himself from the marketplace of the products involved.

In order to remove economic barriers imposed upon the small pesticide formulators, (average gross sales of firms are $2,750,000)* it is necessary to amend Section 3(c)(1)(D) to do away with data compensation. Many of these corporations currently involved in the area of formulation are corporations that evolved in the 50s, 60s and early 70s which based their business upon the registration practices of EPA and its predecessor, USDA, issuing "me too" registrations. The early practice of registration for the formulation industry, as instituted by these two agencies, was to issue a registration on a pesticide product which was similar to a product upon which a registration had already been issued. This action was sanctioned by the basic pesticide producers** as a means of expanding their penetration into the pesticide market.

As patents began to expire in the early 70s, it became evident to the large producers that they would be losing a sizeable portion of their control of the market by allowing this practice to continue and in 1971 and 1972 approached Congress with the amendments to FIFRA which were passed on October 21, 1972. These amendments created a means to limit competition and protect the use of data by others attempting to obtain "me too" registrations. Hence, they have drastically affected the formulating industry by pulling the small producer into the entire scheme of the law which forces them into a data compensation situation.

Competition on any commodity is desirable as it tends to lower the cost of those products to the ultimate consumer. An example of this is the expiration of the herbicide atrazine patent in 1976. Prior to expiration of this patent, the price of atrazine 80W to the farmer was $2.33 per pound.*** When the patent expired in mid '76 and both imports and new producers in the United States came onto the market, the price of atrazine dropped to $1.66 per pound. Based on an annual U.S. usage of approximately 100 million pounds per year, this reduction in cost resulted in a net savings to the American consumers of over 50 million dollars per year.

As can be seen by the above example, if additional competition enters the market and if the price of the product is allowed to decrease, the savings to the American consumers can be sizeable. It also shows that an increase in competition forces down the price that the original patent holder enjoyed due to his patent protection.

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* FIFRA: Impact on the Industry; EPA Office of Pesticide Programs; March 7, 1977; Pages 6-7.

** Incremental Cost Impacts of the 1972 Federal Insecticide Fungicide and Rodenticide Act as amended; January 1976; EPA-540/9-76-002; Page 120.

*** Ciba-Geigy Corporation vs. Farmland Industries, Inc., initial decision; FIFRA comp. dockets Nos. 33, 34 and 41, United States Environmental Protection Agency Before the Administrator; August 19, 1980; Page 31, Footnote 42.

The question must be asked as to whether a corporation should enjoy additional rewards for its test data above and beyond that of its market and that which is protected by its right to market exclusively under a patent. The data which is generated is generated for the purposes of protecting man and the environment and assuring that the products sold will not defraud the public through nonperformance. The original data generator recovers his cost of data through the selling of the technical product, the selling of his formulated products to the consuming public, and through the additional marketing of his technical materials to the formulating industry. Is it right, therefore, for the data generator to reap additional benefits under the data compensation provisions of Section 3(c)(1)(D)?

With this in mind the amendments to Section 3(c)(1)(D) contained in S. 2620 will provide for increased competition while at the same time allowing the small producer to stay in the market by eliminating the barrier to market entry of data compensation.

Section 3(c)(2)(B)

During the past year the Administrator has begun a program of calling in additional data for purposes of supporting registration of existing pesticide products. While this call-in is made for the purpose of filling gaps in the existing data package of these pesticide products, it has often been questioned as to whether or not the data is actually required to support the safety and efficacy of these products which have been on the market for several years.

One example of the above is the recent data call-in for 2,4-D products. Even after consulting with the Scientific Advisory Panel and having disagreement from them in several areas, the Administrator went forth and called in data which the Scientific Advisory Panel did not believe was really necessary. This data call-in program will cost the industry an estimated $3,000,000 to supply the data which the Administrator has requested. While the industry has no problem with supplying this data nor with providing information when actually required for the purpose of supporting the continued registration of pesticide products, it does not feel that it is necessary to provide data on the basis of a scientific "witch hunt" and, therefore, we are recommending that a change be made in Section 3(c)(2)(B)(i) to require that if the Administrator and the Scientific Advisory Panel determine that additional data are required, that such data will be produced by the regulated body instead of allowing the request for this data to be the independent determination of the Administrator.

We are further suggesting that a change be made in Section 3(c)(2)(3)(ii) which will require that when data are requested by the Administrator to support an existing registration, that such data will be generated by all registrants of that pesticide in a joint venture thereby meeting the mandates of the 1972 FIFRA to conserve financial and testing resources.

In addition to this, the proposed amendments will also allow the small producer of pesticide products to share in the production of large blocks of data which many times can run into millions of dollars without placing an undue financial burden upon them which would be an economic barrier to their continuation in business.

Small producers could not support an independent research project, similar to the one on 2,4-D mentioned above, under their own financial resources while a major basic producer could undertake such an action independently and be able to lock out the small producers by placing an unreasonable economic barrier in front of them.

By providing for joint development of this data the small producers will have an opportunity to share in the overall production costs thereby reducing their overall financial involvement and at the same time affording the same opportunity to the major producer of a pesticide.

Such a program will allow additional resources to be made available for research into new uses of existing compounds in the development of new and safer pesticide products.

"CITE-ALL" - SECTION 3(c)(2)(C)

Currently the Administration has taken the stance that in order to register a pesticide product, EPA must rely upon the entire volume of data contained within its files. Such reliance forces a registrant, whether a small formulator or basic producer, to often times rely upon the same test produced by different registrants and offer to pay compensation accordingly; thereby, requiring him to pay compensation more than once for multiple pieces of test data which each under its own validity would provide the necessary information to the agency.

The amendments being proposed to Section 3(c)(2)(C) provide that a registrant has a right to either submit his own data, cite existing data in the possession of the agency or any combination thereof (allowing him to submit portions of data and cite other portions of data contained within the agency's files) to satisfy the requirements of section 3 registration. Thereby, meeting the mandates of FIFRA to provide safe and efficacious products and at the same time reducing the financial burdens placed upon pesticide manufacturers and formulators.

FIFRA - SECTION 24(a)

The PPA has taken a position on changes in Section 24(a) in the past and is still maintaining the same position. We do not want to abrigate States Rights however our membership of smaller companies cannot exist under 50 mini kingdoms of EPA with each one devising their own requirements for registration of pesticides.

We supported the changes in H.R. 5203, Section 24(a) but felt that these proposed changes did not go far enough. There was limited benefit to Agricultural Chemicals, and limited benefit to our membership of the smaller producers.

Prior to Federal recognition of the chaotic state of the U.S. Highway system, there was no uniformity of the system. Congress recognized the need for change and was forced to pre-empt States Rights in order to obtain needed standardization. Congress did this because, with 48 different State Highway Departments there were no standards for road signs, route signs, caution signs and this endangered the health and safety of the American people. Other examples of needed Federal preemption where Congress responded, include food inspection (meat and poultry), blue sky laws, price supports, grain inspection, and meat grading. The desire to protect public health became the purpose for the precedent of uniformity. Uniformity and standardization is one reason we desire changes in Section 24(a).

Those who wish no changes in Section 24(a) continue to misinterpret our aim in requesting such changes. We wish to clearly state that we are supporters of States Rights however, some changes are necessary for both uniformity and for the benefit of the agricultural community as a whole.

Certain States desire to review data submitted to EPA prior to issuing a State Registration on a Federally approved label. This is almost an impossibility for the small producer or formulator. The data is not available to the small producer even if he pays compensation for that data. (EPA is permitted to utilize that data internally but is not permitted, under the current law, to release that data to the individual who has paid compensation). Therefore, registration in certain states cannot be obtained. An economic lockout can occur in this type of situation.

PPA would like Section 24(a) changed enabling a state desiring data that is not available to the registrant to obtain the data which could be furnished by EPA.

We also realize that situations exist where additional data may be necessary to evaluate a given pesticide due to special local concerns or needs - over and above the data necessary for a Federal Registration.

Although this is an additional burden, especially on the small producer, our members would be willing to generate these data as long as the data is really needed. We feel that EPA should have the authority to judge the need for such data so that a state could not be arbitrary and capricious in their demands.

PPA would support a state's request for such data on the above conditions and in this way, the state's and PPA's objectives both can be reached.

We would appreciate your consideration of Senator Hayakawa's amendment S. 2621.

STATEMENT OF EDGAR W. DUSKIN, EXECUTIVE VICE PRESIDENT, SOUTHERN AGRICULTURAL CHEMICALS ASSOCIATION, DAWSON, GA.

I am Edgar Duskin, Executive Vice President of the Southern Agricultural Chemicals Association (SACA). Our Association is an independent regional trade association representing the formulators, distributors and manufacturers of agricultural pesticides sold in thirteen southern states running from Delaware-Maryland across the South to include Arkansas and Louisiana across the Mississippi. Though our membership includes on a regional basis most of the companies which are members of NACA and PPA the bulk of our membership consists of independent regional and intrastate formulators and distributors. Most of our formulator members are those who simply are trying to make a living by buying registered technical pesticides from the best source possible, making and selling their own end-use product. Because of our diverse, broad based membership, representing all factions and levels of our industry, SACA believes itself to be in the unique position of speaking for the little people in the industry as well as understanding and generally supporting the views of the basic manufacturers and others.

What the little people want, is the ability to buy products at the most advantageous price and to be able to formulate and resell to dealers and even farmers—without being involved controversy over registration data, compensation, etc. High interest rates, thin profits and controversy are their enemies. Anything which increases their costs affects them seriously and rapidly.

Compromise among industry factions and reasonable understandings with environmentally oriented groups are of utmost importance in holding down costs through creation of a climate involving less litigation and a less adversarial approach.

The new approaches we have seen in EPA are most welcome to our membership, particularly the speed up in the registration division and settlement of long standing disputes.

The compromises within the industry and with EPA to FIFRA Section 3 as proposed in S-2620 and the House Agricultural Committee Bill are, a major step forward. We believe their implementation will do much to spur innovation and speed the development and earlier marketing of new products which are the distributor's lifeblood and best source of profits.

The proposed changes to Section 10 are necessary companion pieces to the Section 3 changes. We urge their adoption as well. While many of our members would prefer the House version of "New Uses" where no exclusivity is given for new uses of pre-1978 registered products, are pleased to see a compromise with EPA and among industry toward clairiying when exclusivity starts, if such is deemed desirable. We like the "Three Clock" idea. What we especially would not like to see would be attempts to use the necessarily vague wording as a basis for further litigation which could stymie registrations for innovative new uses of old products which are beyond patent protection and which heretofore have had only limited exclusivity protection.

Though not a part of S-2620 per se and because we are not a part of tomorrow's panel on Section 24A we would like to comment briefly on that aspect at this time. First let me say that we are strong and firm believers in the right of states to run their own affairs to set standards demanded by their citizens—so long as such are reasonable, not capricious and are based on an identifiable need. We believe a federal registration and the data submitted to support and obtain it should be acceptable "a priori" in any and all states. This data should be available to a state on demand providing it is given the same protection as required under federal law. If a state deems that it has a peculiar or unique situation which would require additional data or testing it should have the right to ask for it—but not to use such demand to stall registrations. If a product is federally registerable automatically it should be, at least, conditionally registerable in any state. If a registrant questions the scientific necessity of the demand of a State for additional data, there should be some mechanism for arbitration or higher review, perhaps the Science Advisory Panel (SAP). We do not believe implementation of these principles, in any way infringes on a State's legitimate rights. On the contrary their enactment would provide for uniformity, enhance commerce to the benefit of agriculture and the economy as a whole, while not in any way increasing risks to man or the environment. S-2621 is a move in this direction. We urge its adoption.

Though not contained in S-2620 or S-2621, The House Ag Committee Bill contains one provision, and barely missed containing another, which we believe are not constructive, will lead to more controversy, will do nothing to add to protection of man or the environment and which are almost an open invitation to lawsuits. We wish to state our opposition to them now in the hope that, if proposed to be added to the Senate Bill our views will be on record. These are the proposals which would add language to Section 12 and 14 of FIFRA spelling out in great and tedious detail the protections for a worker who "exercises his rights under the Act". We believe this is absolutely unnecessary. Worker rights are adequately protected under existing statutes.

Similarly the proposed revisions to Section 25 of FIFRA which would require EPA "if new regulations are found to be necessary" to promulgate within one year regulations for worker rentry, storage, warehousing etc. of pesticides. If passed, in our opinion, one would see immediate pressures upon EPA to force promulgation of these additional and mostly unneeded regulations within one year. EPA should not be forced to publish regulations in these areas within any mandated time frame.

Amendments to section 16 of FIFRA which would allow "private right of action" directly in Federal District Court, by-passing state courts by "any person claiming to be aggrieved by the use of pesticides in violation of FIFRA" were proposed, but narrowly defeated in the House Agriculture Committee. Such amendments are a clear attempt to by pass the entire state courts system and if implemented, could virtually bog down farming operations with injunctions and jurisdictional disputes. If such are proposed to be added to the Senate Bill, we wish our opposition to be on record.

In summary, our segment of the Agricultural Chemicals industry urges passage of S-2620 and S-2621 subject to the cautions mentioned. We recommend non passage of amendments which may be proposed following the pattern or language contained in or discussed in the House Agriculture Committee bill relating to Sections 12, 14, 16 & 25 as discussed herein.

STATEMENT OF DR. FRANK E. GUTHRIE, NORTH CAROLINA STATE UNIVERSITY, ON BEHALF OF THE MARCH OF DIMES

My comments are directed to the proposed amendments in H.R. 5203 and specifically to changes proposed for Section 10(d) concerning "innovative methods and technology."

The problem that specifically concerns me regards birth defects possibly caused by chemicals in the environment. The scientific explanation for birth defects is in its infancy. The U.S. population was largely spared the unanticipated and tragic events following use of thalidomide. This event did, however, serve one important cause to this nation. It clearly demonstrated that chemicals could cause birth defects and that chemicals were not then receiving adequate scientific scrutiny for possible birth defects. Since the thalidomide incident, a considerable effort has been mounted in the United States to avoid a repeat performance with other chemicals as evidenced by the third edition of Shepard's "Catalog of Teratogenic Agents" and Schardein's "Drugs as Teratogens."

Such research is painfully difficult and slow to accomplish, and it is complicated by differences among species, differences in metabolic patterns, differences in dosage, differences in time from the insult to the adverse event, etc. Above all, the small, possibly chronic, doses necessary to a birth defect have thus far defied detection. A large number of chemicals, including pesticides, have shown adverse effects (via a birth defect) from large doses, but such doses are atypical of normal exposure. The word "unanticipated" (as mentioned in the next to last paragraph on page 542 of report no. 97-566 of Mr. La Garza's committee) is the word that is the key to the problem. The scientific community can ascertain the anticpated results of larger doses with some certainty, but the "unanticipated" effects (as with thalidomide) are more difficult to ascertain.

Every attempt possible must be made to circumvent such untoward possibilities. Additional scrutiny, not less scrutiny as proposed by this bill's amendment, seems in the public interest. If industrial companies are permitted the luxury of concealing facts learned from "innovative methods and technology" to a segment of the public, one additional safeguard has been removed. Such restrictions cannot possibily aid the discovery of health hazards of chemicals, and it certainly might decrease the possibility of detection of an unanticipated effect at an earlier date. Obviously no chemical company and no legislative body wants to be a party to accidental release of a chemical which might cause a birth defect. Thus, increased, not decreased, surveillance seems desirable. The 5-year period of grace requested by the amendment may appear to be a short period economically, but it is untenable when it relates to suppression of data that might avoid health hazards to the public.

It seems appropriate to note that the changes in the scientific process relative to amendment of Section 10(d) were apparently added to H.R. 5203 just before final markup in the subcommittee and without comment from the scientific community (an input by the chemical industries without proper debate). Also, it should be noted that the Scientific Advisory Committee appointed to serve as the scientific advisor for FIFRA was not consulted relative to the proposed amendment. Just what purpose is served by avoiding an input by the very Scientific Panel appointed to guide FIFRA (and the American public) regarding pesticide hazards, eludes the writer.

If one carefully examines the proposed amendment (page 202, under (B) Innovative Methods . . .), an unfortunate vagueness is apparent. The innovative methods will be made available to scientists acting on behalf of Federal or State agencies, independent scientists working in the field to which the data pertain, and scientists and staff representatives acting on behalf of non-profit health, environmental, or labor organizations but shall not otherwise be available to the general public. However, just who defines this group of individuals is not readily apparent. If someone from this "approved" group were to share the information with what he felt was a qualified scientist, one (perhaps both) might be subject to a $10,000 fine or one year's imprisonment. This certainly reduces effective examination of possible health hazards as scientists may not wish to take the chance of being in an unauthorized category. On the other extreme, the bill might well intend that other scientists (not specifically named) would be welcome to the data. The vagueness is unfortunate.

One can surely sympathize with the problems of industrial companies regarding compliance with U.S. laws. By so-doing some information may be leaked to competitors, especially in foreign countries. This is one of the outcomes of vigorous examination of health effects for the public in a democratic society. Attempts to restrict freedom of information may bring short range benefits to part of society, but it will, in the long term be a detriment to the majority.

I recommend that Section 10(d) be modified to include availablility of testing data to all segments of the general public to maximize scientific scrutiny of chemicals which might cause birth defects.

STATEMENT OF JACQUELINE M. WARREN, ON BEHALF OF NATURAL RESOURCES DEFENSE COUNCIL, NATIONAL WILDLIFE FEDERATION, AND ENVIRONMENTAL DEFENSE FUND

Introduction

The Natural Resources Defense Council (NRDC) is a national non-profit environmental organization supported by 45,000 members who are dedicated to the wise use of the nation's land and water resources, and to the protection of health and the environment. Since its inception in 1970, NRDC staff attorneys and scientists have been involved in administrative, legal and legislative efforts to control involuntary exposures to toxic and especially cancer-causing substances in the environment.

The National Wildlife Federation, with over 4.2 million members, supporters and affiliate organizations in all 50 states, Guam, Puerto Rico and the Virgin Islands, is the nation's largest conservation organization.

The Environmental Defense Fund (EDF) is a private, non-profit national organization of approximately 45,000 scientists, lawyers, economists and others interested in finding scientifically sound solutions to environmental problems.

All three organizations have monitored the implementation of FIFRA for many years and we welcome this opportunity to present our views on amendments to FIFRA in 1982.

The 1978 amendments to FIFRA were carefully crafted to remedy persistent obstacles to implementation of the major revisions to FIFRA that were enacted in 1972. The 1978 amendments were considered and debated at great length, and the legislation that was ultimately passed represented compromises and accommodations that were accepted by all of the various interests concerned. In general, we continue to support strongly the remedial amendments of 1978. Since implementation of certain provisions, such as those providing for public disclosure of health and safety data underlying pesticide registrations, has barely begun and has not yet been demonstrated to be problematical, we believe that major changes to the Act in this area are premature and unnecessary at this time. The following is our analysis of S.2620 and S.2621 as well as proposals for changes to FIFRA we believe are necessary to guarantee the right of members of the public to participate in pesticide regulatory proceedings at EPA, and to protect public health and the environment.

S.2620

I. Section 10: Restrictions on Public Disclosure of Health and Safety Data Supporting Pesticide Registrations

The 1978 amendment to section 10, providing for disclosure of health and safety data underlying pesticide registrations, was the result of a carefully-weighted effort to balance the concerns of both manufacturers and the public regarding data disclosure. The accommodation that was reached was acceptable to all of the major parties, including NACA, and was designed to protect essential trade secrecy data while disclosing data required to assess potential dangers to man and the environment. As the Senate Report on the 1978 amendments states,

> This bill will solve the problems by clearly defining the limits of trade secrets while assuring the public's right to know and also recognizing the cost of data development and the need for cost sharing among registrants. (S.Rep.No.95-334, 95th Cong., 1st Sess. 4(1977)).

A similar statement appears in the House Report:

> H.R.8681 also clarifies the trade secret provisions of the Act by balancing the legitimate right of the public to know the basis for agency decisions and the right of a business to see that the manufacturing process and other trade secret information controlled by the Act are not disclosed for the commercial advantage of competing business interests. (H.Rep. No.95-663, 95th Cong., 1st Sess. 18-19 (1977)).

Both the debates and the Committee Reports on the 1978 amendments well document that one of the principal objectives in enacting the provision for disclosure of health and safety data underlying pesticide registrations was protection of public health. In providing for public disclosure of such data, Congress sought to remedy the fact that EPA has not done an adequate job in assessing the validity of the health and safety data underlying pesticide registrations. At the same time, the disclosure provisions constitute Congressional recognition that the public has both a right to see those data, and a role to play in evaluating and ensuring that EPA's pesticide regulatory and registration decisions are made on a sound scientific basis.

The legislative history of the 1978 amendments also shows plainly that both Houses of Congress were acutely aware of the pesticide industry's contention that disclosure of allegedly "trade secret" health and safety information might have a severe adverse impact both upon their competitive positions and upon innovation in pesticide research and development. The same arguments made here by NACA, _e.g._, that disclosure of data would reduce the incentive to innovate, "destroy" valuable trade secrets, and deprive their members of valuable competitive advantages, were made in 1978 and given serious consideration at that time. Both Houses overwhelmingly resolved the issue by requiring both public disclosure and _compensation_ for reliance on the data by competitors seeking pesticide registrations.

Thus, the 1978 amendment to §3 of FIFRA provides that all health and safety data submitted by registrants subsequent to December 31, 1969, cannot be used to support any other application for registration unless the applicant and the data submitter either reach mutual agreement as to the amount and terms of compensation, or else submit to binding arbitration. (See §3(c)(1)(D) of FIFRA as amended in 1978). The amendment further provides that entitlement to compensation would continue for 15 years following the date of submission of the data. In addition, the 1978 amendment to §10 of FIFRA excepts legitimately trade secret information from routine public disclosure in order to "preserve the right to trade secret treatment of a firm's confidential manufacturing and quality control processes, as well as the identity of the various inert ingredients which are used to formulate end use products and testing methods by which inert ingredients can be analyzed." (123 Cong. Rec. S13095 (daily ed., July 29, 1977)).

The clear compromise embodied in the data disclosure provisions enacted in 1978 was well-characterized by Senator Leahy:

> [B]y making the health and safety data open to public scrutiny we are not allowing free use of that data by competitors. If a registrant wishes to use the data generated by another company to support their registration then he must pay compensation for the data if such data was submitted to EPA less than 7 years before that time. The committee believes that this procedure will allow the registration process to function because an agreement must be made, either voluntarily or through mandatory binding arbitration. Such a mechanism protects the data developer's right to recover his data generation costs while guaranteeing small companies entry to the market and protecting them against an unfair competitive situation. (123 Cong. Rec. S13091,(daily ed. July 29, 1977)(emphasis added)).

Section 5 of S.2620 would amend Section 10 to impose substantial restrictions on the public's access to use and disclosure of pesticide health and safety data. NRDC, the National Wildlife Federation, and EDF participated in the House Agriculture Committee's consideration of various §10 amendment proposals, and strongly urged that §10 be retained as enacted in 1978--since the provision was tied up in litigation for 3 years and has never been implemented. Representatives of the pesticide industry persuaded the House Committee that the theoretical competitive harm that might result from full disclosure warranted some amendments to §10. The draconian proposal NACA advocated--access only to industry-prepared summaries of studies to be read in a policed reading room in Washington--was rejected. Thereafter, following extensive negotiations between certain of the interested parties, a partial compromise accommodating industry's concerns was reached. The amendment adopted by the House Committee therefore represents only a partially agreed-upon compromise.

From our point of view, the House's §10 amendment still cuts back substantially on the disclosure promised by the 1978 amendment but never yet realized because the pesticide industry challenged the provision in a spate of lawsuits between 1978 and 1981. Now that they have lost most of those challenges, and Congress' authority to legislate disclosure of pesticide health and safety data has been affirmed, we are here again to accommodate the industry's so far undocumented allegations about the harm they say--as they did in 1978--may result from disclosure. We believe a heavy burden of proof must be borne by those advocating a change in the law, especially where the provision in question has yet to be implemented. Instead, we have been placed in the anomalous position of urging Congress not to amend an important and untried section of FIFRA, one that was enacted after extensive deliberation only a few years ago.

The Senate bill was introduced with a statement by the Chairman that it "is the product of a great deal of effort by the pesticide industry, public interest and environmental organizations and others." The genesis of that effort has been described above. To the extent that the House version of §10 represents any consensus, it is partial, and integrally dependent upon inclusion of all of the various provisions that made up the component elements of the compromise. The §10 amendment in S.2620, however, differs so significantly from the House version in major respects and leaves out so much of our part of the bargain, that we must strongly oppose it.

Omission of the Principles Governing Regulations to Implement §10

First, the carefully negotiated principles that were designed to guarantee the public full access to health and safety data, and to protect against arbitrary withholding of data by EPA, have been deleted from the bill. These principles represent the very heart of the agreement that was reached among various of the parties on the House side, although strong disagreement over the innovative methodologies provision remained. Without the clear guarantees of access to and use of data, and the proscription on EPA discretion in implementing §10 that the principles set forth, there is no longer any agreement.

Since the specific Congressional intent embodied in the principles is not present in S.2620, the ambiguities and uncertainties in the statutory language will result in extensive litigation that could effectively foreclose data disclosure to the public for the indefinite future. Even with the principles included, the prospect of litigation by the pesticide industry that could prevent disclosure for the next several years, is a real one. Without the principles, the potential subjects for litigation over the meaning of the new language are multiplied while the likelihood of achieving public access to pesticide health and safety data is greatly diminished.

Innovative Methodologies

The proposal to withhold from scientific and other public review data falling into the vague and general category of "innovative methodologies" was never subject to hearings before the House Agriculture Committee. Thus, the implications of registering pesticides on the basis of product chemistry, residue chemistry, environmental chemistry or metabolism data generated by so-called "innovative methodologies," have not been adequately investigated. These data often pertain to the environmental fate of pesticides and constitute critically important information regarding human and environmental exposure.

To the extent that the absence of pesticide residues in various environmental media or in living organisms is established by means of an "innovative methodology," that methodology should be subject to the normal scientific peer review process. That process involves free critical discussion among scientists as well as replication of experiments in order to confirm results. In our view, the withholding of "innovative methodologies" from this process for five years is both scientifically indefensible and poor public policy.

The history of pesticide registrations supported by invalid-because-not-peer-reviewed studies is well documented. Indeed, EPA is presently in the process of reviewing a very large number of studies, the validity of which has been called into serious question because they were conducted by Industrial Biotest Laboratories (IBT). Officials of IBT were recently indicted for falsification of pesticide and drug registration data. It has been estimated that 1/3 to 1/2 of currently-registered pesticides are supported by IBT data. Given this history, we have serious concerns about legislating an exemption from the normal scientific peer review process for data bearing directly on human and environmental exposure to pesticides.

It was only our strenuous objections that led to imposition of a finite rather than an infinite period for the exemption as well as to inclusion of a relatively cumbersome procedure for challenges to the "innovative" designation. However, these modifications do not alter the fact that the pesticide industry is seeking special protection for an imprecisely defined and potentially large body of information concerning the environmental fate of pesticides, although they have made virtually no case for the need for this protection.

Any competent scientist would testify to the importance of peer review to validate test methodologies and confirm results. Yet, the "innovative methodologies" provision of S.2620 would effectively prevent this process from occurring despite the importance of the information involved for accurate assessment of the exposure potential and environmental fate of pesticides in current use or to be introduced in the future.

Not even EPA can adequately evaluate truly innovative methodologies without peer review. In large measure, the absence of peer review in the past gave rise to many of the potentially serious problems, both environmental and administrative, we have and continue to face from pesticides supported by invalid data. Enactment of the "innovative methodologies" provision would be tantamount to institutionalizing the mistakes of the past. It should not be done without the most careful deliberation and with full recognition by the Committee of the possible consequences to the health, environment and economic well-being of those who use or are otherwise exposed to pesticides registered on the basis of un-peer reviewed data. We urge the Committee to delete the innovative methodologies provision in its entirety.

Another provision of the proposed §10 amendments which is troubling is the "civil action" section. That section, which authorizes actions by data submitters for treble damages against persons who violate or threaten to violate §10, should be directed at preventing competitors of data submitters from misusing the data in violation of the statute. If liability for treble damages is directed at all members of the public, it will have a chilling effect on independent scientists and other members of the public who might publish an article about the data for a fee and thereby run the risk of an inadvertent violation "for a commercial purpose." To remedy this problem, the section should be amended as follows:

> "(h) Civil Action.- Any data submitter under this Act, who is or may be adversely affected by a violation (or threatened violation) of this section by any person (other than a Federal or State official) who is acting wilfully in furtherance of a commercial purpose involving the production, registration, distribution or sale of a pesticide, may bring an action in an appropriate United States District Court...."

The underscored language appears in the Penalties section and should also be included here.

II. Guaranteeing the Right of Members of the Public to Challenge Pesticide Regulatory Decisions in Agency Hearings

As a result of the 1972 amendments, §6(b) of FIFRA provides that "a person adversely affected" by a notice of intent to cancel a registration or change its classification, is entitled to request a hearing before the Environmental Protection Agency (EPA). Every major pesticide cancellation and suspension decision made by EPA since 1972 has involved such a hearing, and in virtually every case, environmental, labor and farmworker organizations have been equal participants along with registrants and user groups, in airing the issues involved.

It is clear that Congress intended that all persons who believe their interests to be adversely affected by a proposed EPA cancellation action would be full participants in the Agency hearings. As the Senate Report on the 1972 amendments makes clear,

> The Agriculture Committee bill...permits any citizen to initiate cancellation proceedings, obtain judicial review of every action and inaction he disagrees with, and intervene in every proceeding.... (S.Rep.No.92-838,Part II, 92nd Cong., 2d Sess. 39 (1972) [emphasis added]

It should be noted that the Senate language on "adversely affected," to which the preceding quote refers, was adopted as the final conference language in 1972.

In 1979, however, EPA reinterpreted the language of §6(b) to mean that only registrants and users of pesticides, i.e., those with an economic interest in the continued registration of a pesticide, can be "adversely affected" by a notice of intent to cancel. Thus, only those who believe that a notice goes too far can have a §6(b) hearing at EPA. Those who feel that a notice does not go far enough to protect health and the environment, i.e., farmworkers, environmentalists, consumer groups and all other members of the public, are not entitled to a hearing to make their case to EPA.

By re-interpreting the words "adversely affected", EPA has excluded the general public from meaningful participation in pesticide regulatory proceedings. The Agency's position, which represents a complete reversal of its position on this issue for the past 10 years, has been affirmed by the U. S. Court of Appeals. Environmental Defense Fund v. Costle, No. 79-1971 (D.C. Cir. July 17, 1980).

It is patently unfair to exclude members of the public from challenging the adequacy of pesticide regulatory decisions in hearings before the Agency, while guaranteeing the right of the pesticide producer and user groups to challenge the stringency of such decisions. Indeed, the current amendment proposals provide several new opportunities for hearings for data submitters in §3, including the award of attorneys fees in cases involving disputes between submitters (§3(h)(2)(H)), and add a new section guaranteeing that the RPAR process shall not be used "to abridge entitlement [of pesticide producers and users] to a public hearing in accordance with §6 of this Act."

Since the proposed amendments already contain changes to §6(b) of FIFRA, NRDC, the National Wildlife Federation, and EDF urge the Committee to enlarge the §6(b) amendments by restoring the standing of environmentalists, labor unions, consumers and other members of the public to challenge EPA's pesticide regulatory decisions in hearings before the Agency. Under current law there is a great inequity between the procedural rights of registrants and users of pesticides and those who are otherwise exposed to or affected by pesticide use. S.2620 would greatly exacerbate that inequity. Members of the public had the right to request and participate in EPA's pesticide regulatory hearings from 1972 to 1979. They do not have it now. If the commitment of this Committee, and indeed of the entire Congress, to public involvement in and oversight of EPA's pesticide regulatory decisions is to be more than lip service, the right of members of the public to standing in EPA's pesticide hearings must be restored.

The standing issue is not hopelessly complex or technical; on the contrary, it is a simple question of fairness. To assure that members of the public are once again included in the review and decisionmaking aspects of the pesticide re-registration process, we recommended statutory language to clarify that the right to hearings in §6(b) includes all persons adversely affected by the notice. A one-word change in §6(b), accompanied by a clear statement in the Committee report of intent to include environmental, labor and consumer groups, and all other citizens who believe themselves to be adversely affected by a notice, could rectify this inequity. If such a change were made, §6 would then appear as follows:

> §6 Administrative Review; suspension.
>
> ***
>
> (b) Cancellation and Change in Classification.--
>
> ***
>
> The proposed action shall become final and effective at the end of 30 days upon receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time...(ii) a request for a hearing is made by any person adversely affected by the notice.

The grant of "standing" to seek district court review of pesticide regulatory decisions following the interim administrative review under §3(c)(8)(D) does nothing to correct the glaring imbalance in procedural rights under §6(b) of FIFRA. Section 16(a) already provides the right to judicial review of such decisions in district court. What we are seeking here is the right to have administrative review in a §6(b) adjudicatory hearing at EPA. The pesticide industry has the right to request such an administrative hearing when it believes EPA has gone too far in regulating a pesticide. We no longer have the same right to request a hearing when EPA has not gone far enough to protect health and the environment. We therefore urge the Committee to adopt the simple one-word change in §6(b) that will restore the balance and enable the public to participate once again in hearings before EPA involving the adequacy of pesticide regulatory decisions.

III. Proposed Changes to the RPAR Process

Although originally enthusiastic about the RPAR process as an administrative tool to expedite and standardize the reregistration of pesticides, we have been increasingly excluded from meaningful participation as the procedures have become more "back-room." Pursuant to the so-called Grassley Amendment, EPA has been privately notifying registrants prior to initiating an RPAR, and has afforded them a reasonable opportunity to submit data to "correct or clarify" risks associated with their pesticide products. Needless to say, the public has not been involved in this process. S.2620 would formalize this procedure by means of an amendment providing that 90 days prior to initiating an RPAR, the Administrator "shall notify all affected registrants of the risks upon which the proposed review will be based." Registrants "or other interested persons" (who manage to find out about it) may then submit "correcting or clarifying data." Thereafter, a final determination on whether to issue the RPAR or to proceed with reregistration will be made. Consistent with current practice, the public would receive its first notice only after the decision was made.

The procedure just described is a far cry from the full public hearing intended under §6 for decisions concerning the continued registration of pesticides which may cause unreasonable adverse effects on man and the environment, (i.e., RPAR candidates). We believe that the public should be brought fully into the pre-RPAR process because the real decisions on cancellation and registration are apparently being made at this stage. Otherwise we suggest that the Committee seriously consider amending the statute to return pesticide decision-making to the public hearing stage where it was originally intended to occur, guaranteeing at the same time, of course, the right of members of the public to participate as full parties.

S.2621: Federal Preemption of State Pesticide Regulation

We strongly oppose imposition of federal restrictions on the right of the states to require whatever information they deem necessary for the registration of pesticides to be used within their borders. In the area of protecting human health and the environment, Congress has continually recognized the right of states to do more than the federal minimum, and has avoided legislating to restrict the states from enacting more stringent requirements. No compelling, overriding federal interest exists in this area that would warrant such a dramatic departure from past legislative practice.

S.2621 would preclude a state from taking precautionary steps against contamination resulting from the use of a pesticide. For example, proposed §24(a)(2)(B)(i) would require a state to obtain "significant factual information which reasonably supports the conclusion that the use of any pesticide...within the State presents a concern...." Thus, states such as New York and California would not be able to require data on the propensity of a pesticide to move through soil and contaminate groundwater until after such contamination occurred and could be documented. Both states have suffered from serious groundwater contamination resulting from pesticide use or disposal. EPA does not consider this aspect of pesticide use in the registration process although S.2620 contains a provision authorizing EPA to impose groundwater protection restrictions on pesticide use in the future. We strongly oppose any amendment that would require the states to wait for adverse effects to occur before action could be taken to protect health and the environment.

The proposed §24(a) amendments would also require the states to overcome many administrative obstacles before additional data relating to the health and environmental effects of a pesticide could be requested. Considering the well-documented shortcomings of EPA's pesticide regulatory program as well as the repeated instances of pesticide hazards being detected first at the state level, we wonder how the public interest is served by preempting the states from doing any more than EPA to protect their citizens against injury from pesticides.

A good case has not been made by the pesticide industry demonstrating that interstate commerce in pesticides has been disrupted by California or any other state. Indeed, a more persuasive case could probably be made of EPA's inability to do the job adequately. We therefore urge the Committee to continue the present policy of §24(a) and to reject the intrusion on the right of the states to protect the health and environment of their citizens that enactment of S.2621 would create.

Other Amendments to FIFRA

NRDC, the National Wildlife Federation, and EDF strongly support five additional amendments to FIFRA that will be described in testimony by other witnesses:

1. Public disclosure of "inert" ingredients of pesticides. The term "inert" under FIFRA means pesticidally inert; it does not mean biologically inert. Since some "inert" ingredients can be extremely toxic, such as vinyl chloride, we believe their identity should be publicly disclosed. Because exposure to pesticides necessarily includes exposure to potentially toxic "inert" ingredients, the same public right to know should be recognized for the identity and toxicity of "inert" ingredients as has been the case for the active ingredients.

2. Private right of action. The right of persons injured as a result of violations of FIFRA to seek injunctive relief and damages in federal court should be added to §16 of FIFRA. S.2620 would create such a private right of action for registrants against persons violating §§3 and 10 of FIFRA, and even provides for awards of attorneys fees. It is unfair for Congress to provide such rights only for pesticide producers while denying the same treatment to persons who are injured as a result of pesticide use in violation of FIFRA.

3. Safe working conditions. A provision comparable to the House amendment to §25 should be added to require EPA to promulgate regulations establishing minimum field re-entry standards, spray drift controls, and requirements for instruction and training of persons handling pesticides.

4. Employee remedies. A new subsection (c), identical to that in §7 of the House bill, should be added to §14, the "Penalties" section of FIFRA, to provide procedural remedies for employees who believe themselves discharged or discriminated against for filing complaints concerning alleged violations of FIFRA.

5. Protection of children working with pesticides. We also support requiring the Administrator of EPA to consider the effects of a pesticide on children when registering or imposing restrictions on use of the pesticide. At the present time, pre-adolescent children are permitted to work in agriculture but no special consideration of their susceptibility to injury from pesticide exposure is presently required in the registration process.

We appreciate this opportunity to present our views and recommendations on amendments to FIFRA this year.

Statement of Jay Power, Legislative Representative, American Federation of Labor & Congress of Industrial Organizations

The American Federation of Labor and Congress of Industrial Organizations has a direct and immediate interest in the reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act. Members of AFL-CIO affiliated unions face serious risk of disease, injury and death from pesticide use, application and manufacture. For farm workers and pesticide applicators FIFRA provides the primary occupational health and safety protection, though that protection is far from adequate. For these and other workers FIFRA also provides the major vehicle for the development of health and safety data on pesticides and access to this information. Thus, the FIFRAct and its effective implementation are central to protecting workers from pesticide exposures.

Unfortunately, neither the FIFRAct nor its implementations have satisfied worker protection needs. For farmworkers and applicators whose primary health and safety protection from pesticides has been found to rest under FIFRA, protections are largely limited to label instructions with little or no enforcement activity by EPA. Requirements such as routine medical surveillance and exposure monitoring do not apply to exposed farmworkers, nor are there meaningful prohibitions against employer discrimination or retaliation.

The statute and its implementation are also lacking with respect to the release of health and safety data. The FIFRAct allows the identity and other information on inert ingredients to be claimed trade secret, even though many of these ingredients are biologically active and toxic to exposed humans. Provisions of the 1978 Act which theoretically required the disclosure of all health and safety data to the public have been met with industry court challengs, EPA administrative delays with little health and safety data released.

Now in 1982, the Congress has an opportunity to correct many of these deficiencies in the FIFRAct. But neither S. 2620 nor S. 2621 adequately address these problems. Indeed, in the view of the AFL-CIO their passage would greatly erode the minimal protections provided workers and the public against the hazards of pesticides and thus we oppose both bills. Our specific objections are as follows:

1. NO PRIVATE RIGHT OF ACTION FOR WORKERS OR THE PUBLIC

EPA enforcement of FIFRA, particularly in the area of farm worker protection, has always been dismal. Now with federal budget cuts enforcement is sure to deteriorate further. A private right of action for workers and the public to seek relief from hazardous pesticide exposures through the federal courts would provide an independent enforcement mechanism for affected individuals.

S. 2620 has recognized EPA enforcement inadequacies and provided pesticide producers the right to seek not only injunctive relief but damages and attorney's fees as well in cases involving data misuse by competitors. Inclusion of a parallel private right of action for workers and the public to seek the protections they are afforded under the law is only equitable and just.

2. NO EFFECTIVE MECHANISM TO REMEDY EMPLOYER DISCRIMINATION AGAINST EMPLOYEES

S. 2620 has recognized the problem of discrimination against employees who exercise rights related to the pesticides Act and included a prohibition against such discrimination. However, the bill provides no meaningful remedy to employees in the event of discrimination. EPA could fine an employer who violates the law, but there is no provision to allow reinstatement of fired employees or payment of back wages.

For anti-discrimination protections to be meaningful, the AFL-CIO believes that the language adopted in H.R. 5203, the House version of the FIFRA authorization should be incorporated in the Senate bill. The remedy contained in H.R. 5203 is present in all other major environmental statutes—the Clean Air Act, Clean Water Act, Toxic Substances Control Act and Resource Conservation and Recovery Act. Inclusion of this provision in FIFRA merely extends to workers exposed to pesticides the same redress afforded workers who exercise rights under other environmental statutes.

3. NO REQUIREMENTS TO DEVELOP FARM WORKER HEALTH AND SAFETY STANDARDS

Under a 1975 court decision, primary federal responsibility for farmworker and applicator protection from pesticide exposure was found to rest with EPA and not OSHA. But citing ambiguity in statutory authority, EPA has taken no action to promulgate worker health and safety standards on individual chemicals or generic medical surveillance, monitoring or training requirements.

To fill this void in farmworker protection the AFL-CIO favors statutory language placing farmworkers and applicators under the Occupational Safety and Health Act which is directly geared towards worker protection. In the absence of such a transfer, however, Congress must direct EPA to finally develop and promulgate health and safety standards to protect farmworkers and applicators exposed to pesticides.

4. PROVISIONS FOR THE RELEASE OF HEALTH AND SAFETY DATA ARE TOO VAGUE

As this Committee is aware, Section 10 of FIFRA which sets forth requirements for release of health and safety data to the public has been a controversial subject both in the current 1982 reauthorization as well as during deliberations on the 1978 Act. Labor, environmental and farm worker groups believe the language of the 1978 statute is sufficient to protect against the release of trade secrets and misuse of data. Pesticide producers believe greater restrictions on data disclosure and use are needed.

During consideration of the FIFRA reauthorization by the House Subcommittee earlier this year, deliberations between representatives of industry, government, labor, environmental and farmworker groups on Section 10 provisions were conducted. Those deliberations led to the Section 10 language contained in H.R. 5203. The language in the House bill creates a new class of data "innovative methodologies", which is subject to limited access and establishes greater use restrictions for other safety and health data. These provisions are to be implemented through EPA regulations pursuant to guidelines and principles contained in the statute.

The AFL-CIO has not opposed the Section 10 language in H.R. 5203, although we do have serious concerns that the provisions, particularly those concerning innovative methodologies were adopted without any real congressional consideration. In addition we are concerned the adoption of new Section 10 provisions that may be met with court challenges by individual pesticide producers, despite assurances of the pesticide producers trade association.

In the absence of complete legislative history on the Section 10 provision, AFL-CIO non opposition to the House language has been contingent upon inclusion of a detailed statement of principles on the intent of the language in the statute itself. However, those principles which formed part of the House package on Section 10 are absent entirely in the Senate bill.

Unless the statement of principles regarding data disclosure is included in the statute itself, the AFL-CIO must vigorously oppose any Section 10 changes under consideration. We urge this Committee not only to adopt the statement of principles contained in the House bill, but also to provide a full hearing and consideration on the issue of innovative methodologies and the impact of data access and use restrictions on the scientific process.

5. STATES ARE PREVENTED FROM TAKING NECESSARY ACTIONS TO PROTECT THEIR CITIZENS FROM PESTICIDE EXPOSURE

H.R. 5203 contains unfortunate language which sets up extreme barriers to states who wish to go beyond the federal government in requirements for data. Even greater restrictions on state activities are proposed by S. 2621. Federal EPA is given authority to determine what is a local concern an may disallow state requests for data. Strict time frames for acting on registration requests are imposed on states, and political subdivisions of states are provided no rights to seek additional data and take action.

Experience has shown that states need authority to take actions beyond the federal government in order to protect their citizens from pesticide exposures. Indeed federal action restricting numerous pesticides which pose a serious risk has been inadequate or non-existent.

The provisions of S. 2621 (and H.R. 5203) set up a bureaucratic system that will make it impossible for states to gain access to necessary data on which to base their decisions. This language should be withdrawn and provisions of the current 1978 Act governing states rights should be maintained.

In summary, S. 2620 and S. 2621 are geared solely at serving the needs and interests of the pesticide producers. The problems of the public and workers related to the FIFRAct have not been addressed by these bills, and indeed are severely aggravated by these legislative proposals. Amendments to assure worker protection, discrimination protections, a private right to seek enforcement through the courts and provisions setting forth principles for data disclosure are needed. Amendments restricting state activity must be deleted. In the absence of such amendments, the

AFL-CIO must oppose S. 2620 and S. 2621 and seek to maintain the integrity of FIRFA through extension of the 1978 Act.

STATE OF CALIFORNIA,
DEPARTMENT OF FOOD AND AGRICULTURE,
Sacramento, Calif., July 15, 1982.

Hon. JESSE A. HELMS,
Dirksen Senate Office Building,
Washington, D.C.

DEAR SENATOR HELMS: On June 22, 1982, I presented California testimony before the Senate Committee on Agriculture, Nutrition, and Foresty dealing with proposed changes affecting Section 24(a) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Due to time limitations, you requested written response to additional questions. Such response is enclosed.

We hope that you will understand our position of no change in Section 24(a). California's present pesticide registration program provides for the safe and effective use of pesticides by agriculture and protection for rural and urban citizens as well as our environment.

If we can provide additional information, please let me know.

Sincerely

RICHARD E. ROMINGER, *Director.*

Enclosures.

RESPONSE TO QUESTIONS FROM SENATOR HAYAKAWA BY RICHARD E. ROMINGER, DIRECTOR, CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

Question 1. Your department has repeatedly made the claim that California has unique crop and population situations and that these peculiarities justify more stringent pesticide registration procedures. Now, I have traveled through much of our nation, and other than the fact that California's agriculture is bigger, I have seen little to distinguish between Californians and the people of other states. We have agricultural and urban land use side by side all across our nation. In fact, in many states they are much more interrelated. The weather throughout the entire southwestern region of our nation is comparable.

I am curious to hear from you on what facts do you base your claim that "Californians are different?"

Answer. It is not the department's position that "Californians are different," but rather that the overall California environment is unique and requires special consideration if its citizens are to be protected from adverse impacts which might result from standard use practices established on nationwide generalities. We produce more than 200 different food and fiber crops ranging from conifers to cotton and avocados to zuchini. Many crops are produced almost nowhere else in the nation, e.g., almonds, apricots, artichokes, broccoli, brussels sprouts, ladino clover seed, nectarines, olives, pistachios, plums, kiwi fruit, pomegranates, prunes and walnuts to name a few.

California has unique climatic conditions, especially our summers, which are very hot and dry in most agricularally productive areas which affects the environmental fate of many chemicals used in pest managment, sometimes converting them to more toxic products. This is in contrast to areas, such as Florida where citrus is grown similar to California, but where the climate is much different with greater humidity and different soil composition.

A major source of human exposure to persticide residues is absorption through the skin. California's large acreage of specialty corps requiring hand labor means a greater potential for worker exposure. When workers contact treated foliage, pesticide residue is transferred to the skin and can be absorbed into the blood. It is important to know the environmental breakdown products of each chemical and the specific conditions under which each chemical is used. Crop residue studies show that the breakdown rate for some chemicals differs in California from the rest of the nation. Examples of this phenomenon include the slower breakdown rate for parathion in California's citrus orchards versus Florida and the slower breakdown rate of methidathion (Supracide) and azinphos-methyl (Guthion) in California versus other states. These differences are of vital importance and are not routinely accounted for in EPA's evaluation of national use patterns and identification of potential problems.

California's water supply comes from various sources including both surface water and underground aquifers. The extensive network of water delivery systems unique to California, requires special protection to avoid contamination of our water resources which serve both as drinking water for extensive urban populations and as essential irrigation water for our many different crops.

As an example, our department conducted an extensive survey of groundwater which detected small amounts of the nematicide DBCP, which causes sterility in humans and cancer in laboratory animals, in both agricultural and city water supplies. When similar surveys were conducted in other states where DBCP was used, extensive findings of such residues did not occur. Upon further analysis of the problem, it was determined that California is unique in its varied soil types and in the way its aquifers travel from mountain ranges, under agricultural lands and on to cities. Therefore, chemicals capable of traveling through the soil into the aquifers become a threat to municipal water systems. In dealing with this problem, California exercised its rights under FIFRA and continued its suspension of all uses of DBCP which was initiated two years prior to EPA taking similar action.

You note "that California's agriculture is bigger." This, too, presents us with unique situations not encountered in other states. California has more full-time commercial pesticide applicators than other states. This means that relatively large numbers of people employed in this activity receive continuous and extensive exposure to pesticide chemicals on a year-round basis as opposed to other states where exposures are more intermittent and limited for the majority of users.

California's climate also provides a longer growing season, allowing second and third plantings in some areas in a single season. Crop rotation presents additional problems of different chemical combinations applied sequentially to control the varied pests which differ between crops. This presents exposure problems to workers in California and to its citizens distinctly different than encountered in most other states.

For these reasons, the states must be allowed to have access to the kind of data necessary to evaluate the states' individual problems associated with the use of pesticides. Problems may arise based on the volume and extent of exposure experienced withing a state, increasing the risk of encountering those hazards which may be less of a threat elsewhere.

In summary, Californians are not different but their environment is. It is this difference that creates hazards for its citizens which can only be prevented by special evaluation of all pertinent data, assessing not only the hazards themselves, but evaluating possible means of limiting the risks citizens may face based on their total environment.

Question 2. On September 4, 1981, before the House Subcommittee hearing on FIFRA, you stated that it was only the chemical companies that want to see Section 24 changed. Are you aware that the agricultural producers themselves in your state have come out in strong support of legislation to change Section 24?

The following organizations have expressed their support: California Farm Bureau Federation, Western Growers Association, The California Grape and Tree Fruit League, California Seed Association, California Tomato Growers Association, California Forest Protective Association, Agricultural Council of California, and California Food Producers. Mr. Rominger, don't these organizations represent the bulk of the farmers in California, producing every one of the 200 plus commercial crops in the state?

Follow-up: You have said numerous times that there is not a problem with the registrations in California. If that is true why would all of the major agricultural organizations claim otherwise and support this legislation?

Answer. After reviewing our September 4, 1981 written testimony, we are unable to confirm the accuracy of your statement indicating we claimed that only the chemical companies want to see Section 24 changed. It is common knowledge, however, that the proposed amendments to Section 24 were initiated by chemical companies with support solicitated from other organizations.

In spite of the agricultural support for changes in Section 24, we cannot accept the belief that accurately informed growers and grower organizations would knowingly support changes that would make it difficult or impossible to obtain human health risk assessment data pertinent to California use conditions for consideration prior to registration and use of pesticides. It has been our experience that California agricultural producers are very conscientious about the pesticides they use and would not condone using materials which present unreasonable health and safety hazards.

Follow-up We have not attempted to convey that California has not had registration problems. We have stated that we were making progress in our two and one half year program phase-in in terms of budgeting and staffing; and that has now been completed. Our testimony has been geared to the need for additional data; states rights to protect its citizens and environment; and pointing out that delays in registration are, in part, a result of the federal "cite-all" regulation procedures, industry conflicts pertaining to proprietory use of data, and an unwillingness of industry to provide the necessary data to assess efficacy as well as worker health and safety hazards.

Question 3. Continuing on the issue of data summaries. It seems to me that this requirement is most difficult if not impossible to satisfy for the smaller pesticide manufacturers.

Do you think the data summary requirement might be perceived to be an insurmountable barrier for smaller producers?

Aren't you effectively saying that "only the large will survive?"

Who else but the large companies could afford to supply identical data to both EPA and CDFA?

Answer. Pesticide manufacturers do vary in terms of size and volume of business. In California, as well as federally, there is a wide variety of chemical companies that have products registered. We recognize that routine duplication of the complete data package required by the EPA would serve no useful purpose. The data summaries fulfill our needs in most cases. We do not have the staff or the desire to duplicate the federal review process. Our purpose and need for reviewing the summaries of federal data are basically two-fold. First, we have a responsibility to protect California citizens and its environment. Our knowledge of California geographic and climatic conditions, crop/pest problems and history of worker exposure incidents gives us an advantage over the EPA in assessing the risks and benefits of the products' use. Secondly, by reviewing summaries of the federal data, we can determine which additional data are needed to meet California requirements. California's additional data requirements compliment the federal data. An example of this is CAC Section 2370(a) involving the additional data requirement of, "safety related to exposure. (a) Dermal absorption. Each applicant to register a pesticide product that has an active ingredient with an acute dermal toxicity (a federal data requirement) (LD_{50}) of 2000 or less milligrams per kilogram of body weight for a 24-hour period shall submit to the director dermal absorption data."

When viewed in terms of the total time and cost of developing the federal data, requiring submission of a summary of the data should not present a significant problem. In fact, many companies have strongly supported the data summary concept in lieu of submitting copies of all the federal data. We have recognized that within the federal cite-all registration process, registrants who might be "smaller producers" have referenced registration data not in their possession as a means of obtaining federal registration. In some of these cases we understand such data were actually the property of another registrant. As a result of this, we understand that EPA is now considering changes that will require prospective registrants to obtain a letter of authorization from the company owning the data they wish to cite in support of their registration. Such a procedure is currently in effect in California. We have found that it does not have a discriminatory effect on registrants regardless of size or volume of business. We have never entertained the philosophy that "only the large will survive."

Question 4. California requires all applicants for registrations to submit summaries of data submitted to EPA. Under the Federal Data Compensation System, a registrant may satisfy data requirements by referencing previously submitted information, even where that material was produced by another company. The second registrant, therefore, may be relying on test results and summaries which it has not seen, but which it knows satisfy EPA's concerns over the safety of the product. This material is not available to the registrant when it applies to CDFA, and so it can not satisfy the requirement for summaries.

Your office has previously claimed that Section 2360(a) of the California Code takes care of this concern by giving the applicant the opportunity to apply for an exemption from the data summary requirement.

We have evidence that your department has ignored requests for exemptions.

Could you tell the Committee how many exemptions you have issued this past year?

Answer. You are correct in your assessment of the Federal Data Compensation system in which a registrant may satisfy the federal registration requirements without owning or ever having seen the test results. Since they do not have access to the data they cannot supply it to California. In these cases, the registrant can submit a letter from the owner of the data which they relied upon to get federal registration (as required by CAC Section 2369(d)) authorizing the use of the data for California registration. If the registrant cannot obtain a letter of authorization they may apply for an exemption from the federal data summary requirement at the time the application is submitted.

This authority has been in effect only since April 10, 1982. Since that time, we have received one request for exemption which we accepted. If you have evidence indicating that other requests have been made and ignored, we would appreciate it if you would share this information with us. We have, however, on at least two recent occasions suggested to registrants that they could request an exemption from particular data requirements.

Question 5. I am happy to see that we have done at least one thing right in your eyes! I would like to ask you a question on the language in Section 2621 relating to political subdivisions.

Would you please elaborate on what you see to be the need for this language.

Follow-up: Also, could you please discuss the problems you are currently having in Trinity County. . . . I understand they have established two new herbicide regulations, first, they are prohibiting the use of phenoxy herbicides (a concern of marijuana farmers on one side and loggers on the other). And second, they have established a county permit system for the use of hazardous substances.

What is the story on these new regulations, and will the language in Section 2621 take care of the problem?

Answer. Efforts in California to adopt ordinances have sought to ban or severely curtail the use of a pesticide based on local perceptions of toxicity and hazard. The assessment of toxicity, determination of hazard, and balancing of risks and benefits is technically complex requiring the cooperative work of many scientific disciplines. These resources are not generally available to subdivisions of a state. Regulation without such assessment, determination and balancing is far more open to public fears than to rational scientific analsis. While state pesticide programs must be open to expression of local concerns and needs, authority to actually regulate pesticides should be vested in EPA and the states with the resources to balance risks and benefits.

Regarding the Trinity County ordinances, the local Board of Supervisors has adopted Ordinances 368, 368.1 and 370 (attached); the net effect of these ordinances is to severely restrict or prevent the use of all herbicides in Trinity County. Violation of the ordinances is a misdemeanor punishable by a fine of $500 and/or by imprisonment in the County Jail for up to six months.

An ordinance substantially similar to the Trinity County ordinance was held by the court (in *Deukmejian v. County of Mendocino*) to be pre-empted by state and federal law.

In May 1981, the Trinity County District Attorney informed the County Agricultural Commissioner, Paul Smith, that he would enforce Ordinance 370 and that he (the District Attorney) would arrest violators of that ordinance. This put Paul Smith, who, as county agricultural commissioner is an agent of the state in the area of pesticide enforcement, in a position whereby issing permits in compliance with state law would presumably be in violation of the county ordinance. Paul Smith then refused to issue herbicide permits.

As a result, on June 7, 1982, the Attorney General filed a complaint (attached) for the Department of Food and Agriculture against Paul Smith, County Agricultural Commissioner, Michael G. Polka, County Health Officer, and Ronald Barbatoe, County District Attorney. This is the same type of complaint that was filed in Mendocino County.

Paul Smith is a named defendant in the complaint only for the purpose of obtaining a declaration, by the court, to the effect that the Trinity County ordinances are invalid and that the state and federal government have pre-empted the area of pesticide regulation. If the department is successful in obtaining the requested Declaratory Relief, the court will order Paul Smith to obey only state and federal pesticide laws.

The suggested amendments to FIFRA Section 24(a) should eliminate local restrictions on the application of federally registered pesticides. This would be very desirable to prevent further litigation and confusion.

Question. 6. We have heard a number of California registrants complain that there is not clear understanding of what exactly the State of California requires in terms of data and what the official procedures are for obtaining a registration.

I understand that you have been working at developing an "Operational Protocol" for a couple of years. Have you published these "regulations for registration" yet? Have you ever opened the "Operational Protocol" to public comment?

Answer. Article 4 of the California Food and Agricultural Code as well as Article 4 of the Pesticide Registration Regulations are established for the purpose of describing the registration process for prospective pesticide registrants. The Food and Agricultural Code, beginning with Section 12811, provides a description of the procedural aspects of the registration process including designation of those who are required to seek California pesticide registrations. In Article 4 of the CAC, beginning with Section 2360, requires that registration applications be submitted on forms provided by the department and accompanied with the required fees and three copies of the proposed label. The regulations also specify that data in Article 5 beginning with Section 2369 must be provided in cases where such data are applicable to the product being considered. In addition, in cases where the product requires federal registration a summary of the documents submitted to the EPA in support of registration must also be provided.

We have found that some registrants did not fully understand the federal data requirments, especially in cases where such requirements were waived at the time of obtaining federal registration.

The Operational Protocol Manual was to be implemented concurrent with adoption of the 1980 pesticide registration regulations. Shortly after adoption, a decision was made that the Operational Protocol was subject to the California Administrative Procedure Act and needed to be adopted according to the provisions of the Act. As a result, the format and contents of the Operational Protocol are being revised. Our time frame for the manual to be operational is January 1, 1983. The protocols for testing have alays been available to companies upon request, as well as, pre-registration consultation for registrants who wanted clarification pertaining to data or any other California registration requirement.

Question 7. Could you relate to this Committee a brief summary of the conflict between farmers in your state and the Department of Food and Agriculture over pesticide rules and regulations? Now, I understand that there is some tension between your administration and production agriculture. To be sure, this is the result of many things, and some of them, such as the Agricultural Labor Relations Board, are beyond the reach of CDFA. I am curious as to how you view the tensions between your administration and agriculture. Have the farmers been overreacting to things like pesticide registration hang-ups, the Medfly crisis, pesticide use regulations, threats of groundwater management, and the notion of extending "worker right to know" to "consumer right to know?"

Answer. Conflicts between industry and governmental agencies are not unique to California and its pesticide program. These conflicts are well documented over a wide range of programs at city, county, state, and federal levels.

The present visability of the Section 24 amendment has opened a controversial issue and divergent views are to be expected. California agriculture can be viewed, in a broad sense, as an important source of the nation's food and fiber production, or as a collection of individuals concerned about events that affect their livelihood. Not being able to use pesticides that have been relief upon for years, such as DBCP, Tok, and Veg-A-Dex,. is frustrating to farmers. They are concerned about not having the pesticide tools available that they need, but are not advocating the use of pesticides that are detrimental to health or the environment.

The pesticide use regulations, the tremendous concern surrounding a potential statewide infestation, groundwater contamination problems and workers' right to know what hazards they are exposed to in their work place are all issues that impact production agriculture. They are issues that invovle government regulation decisions, are controversial, and regardless of how they are ultimately resolved there remains a difference of opinion and residual tension.

We share an optimistic view that the conflicts and tensions perceived are magnified by the controversial issue before you and are not out of proportion to the every day problems facing an agricultural state such as California.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

My name is Ralph Engel, I am president of the Chemical Specialties Manufacturers Association (CSMA) located at 1001 Connecticut Avenue, N.W., Washington, D.C. I am accompanied today by Mr. Harvey Gold, chairman of CSMA's Government Affairs Advisory Committee, Federal Public Affairs Section, and Mr. Jon Grunseth, vice president of Public Affairs, Economics Laboratory, Inc., St. Paul, Minnesota.

CSMA has a membership of nearly 425 firms engaged in the manufacture, formulation, distribution, and sale of insecticides; disinfectants and sanitizers; detergents and cleaning compounds; automotive chemicals; and waxes, polishes, and floor finishes for household, institutional, and industrial uses. A significant number of these products have pesticidal claims and are, therefore, subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA).

Specifically, CSMA represents the nonagricultural pesticide industry, including disinfectants and sanitizers; home, lawn, and garden insecticides; and a wide variety of other insecticides for home, industrial, and institutional use. We are here today to respectfully request this committee to merge the provisions set forth in S. 2620, sponsored by Senator Helms, and S. 2621, sponsored by Senator Hayakawa, into a single bill and report it out to the full Senate. Of utmost importance is § 1 of S. 2621 which would amend § 24(a) of FIFRA.

I. FACTORS GIVING RISE TO THE § 24(A) AMENDMENT

The pesticide industry, regulated under authority of the Federal Insecticide, Fungicide, and Rodenticide Act, administered by the Environmental Protection Agency, is an extremely diverse industry, marketing not only agricultural use pesticides, but such products as disinfectants and sanitizers, and home, lawn, and garden insecticides. In addition to farmers and other consumers, user groups such as pest control operators, growers, hospitals, and institutions, are similarly dependent upon the ready availability of safe and effective pesticide products. All marketers of pesticide products must, prior to sale, obtain a federal registration from the Environmental Protection Agency. This step alone is not sufficient to permit marketing. States themselves have similar registration programs and manufacturers must obtain individual state registrations prior to marketing within their borders.

A very serious, inequitable, and anticompetitive problem has arisen in the state of California and already threatens to spread to other states. This problem has to do with the failure to process applications for registration in a timely fashion and with the arbitrary imposition of additional data requirements above and beyond those presently required by the Environmental Protection Agency.

Unfortunately, some 80 to 85% of applications for registration have been affected by the state of California's policy requiring the development of new data and additional review of existing data on the same products already registered by EPA and the other states. In requesting such additional data, the state often does not give the registrant any factual basis for the request. In many cases, the state has held the application for more than one year before making an additional data request. The net effect has been inordinate delays in the registration process even for firms that were willing and able to submit the additional data.

Because California has generally treated all applications in the same manner, little attempt has been made to sort out the routine requests for such things as changes in logos, names, fragrances, or colors. This non-selective, across-the-board approach has resulted in applications undergoing extensive, tedious processing and review, most for no legitimate reason. Particularly hard hit by this procedure are small businesses and downstream formulators who purchase basic chemicals for formulation into finished products. These firms first depend upon approval of the basic chemicals and subsequent prompt registration of their own formulations to reach the marketplace in a timely fashion for growing seasons and other specialized uses. The backlog is particularly burdensome to large segments of the industry, many of which are small businesses.

Competition has been stymied. Manufacturers have been prevented from getting products on the market—they are virtually locked out from the California marketplace. Consumers and users have been denied useful and effective pesticide products which have been granted EPA registrations and which are available in other states.

When a company sells and distributes its products nationally, the lack of a registration, as in California, disrupts national distribution and advertising channels and forces segregation of products released into the distribution system.

II. THE EFFECTS OF THE CALIFORNIA PROCEDURES ON INDIVIDUAL REGISTRATIONS AND FIRMS

In preparation for a hearing held by the House Agriculture Subcommittee on Department Operations, Research and Foreign Agriculture on September 4, 1981, in Sacramento, California, CSMA surveyed its membership in order to cite specific examples of abuse of data requests and long registration delays by the state. At that time, one member, a small business, estimated that the inability to register products in the state of California resulted in a loss of annual sales in excess of $200,000 and perhaps as much as $500,000.

Another CSMA firm, frustrated with the length of time an application was pending, sent its representative to the California Department of Food and Agriculture

(CDFA) to track down the application involved. After much searching, it was found in a locker amidst hundreds of others, presumably awaiting its turn in the registration review process.

Specific documented examples of the long periods that the State of California took in reviewing applications for both initial and amended state registrations were provided. Among the many examples, a pesticide registered by EPA in 1979 to control vegetable disease required 483 days for CDFA to register. A liquid pesticide registered by EPA to control lawn disease required 492 days for CDFA to register. An insect spray registered by EPA in 1976 required 594 days for CDFA to register.

Lengthy registration delays have also resulted from applications for the simplest label changes on products already registered in California. It has taken between 15 and 24 months to add a new use for a new pest to the California label even when it has already been approved by the EPA for the same uses or pests. Registration applications, even the simplest labeling changes, have had to go through the entire review process. For the record, CSMA's testimony before the House Department of Operations, Research and Foreign Agriculture Subcommittee describing in detail the delays in the state's registration process is attached hereto as Exhibits I, II, and III.

Initially, the California Department of Food and Agriculture represented to the House Subcommittee that there were no problems in its registration system. Subsequently, however, CDFA stated that recent changes in its regulations and efforts to streamline its registration system have solved these formerly non-existent problems. We have nevertheless continued to seek information from our membership with respect to registrations emanating from the state. The following is a representative sample of current information obtained from CSMA members.

Date of letter and *pertinent comments*

April 20, 1982: "The present law has allowed California to delay registration of . . . [a] Disinfectant for over two years in spite of the fact that the product is registered with EPA. . . . California has asked for tests and data that EPA did not require. They have insisted that the product must be effective against gram-positive germs when in fact pine oil is never effective against gram-positive germs. They have allowed as much as one year to pass without any action or comment on our registration . . . . It is our conclusion that California has neither the personnel nor the technical expertise to fairly administer the present law."

Time Elapsed: Up to one year.

May 24, 1982: "Attached is a summary of our most obvious delays in registrations of EPA registered products in the State of California."

(a) Application for bathroom cleaner originally submitted to CDFA on April 7, 1980; subsequent data package submitted to CDFA, per their request, on July 11, 1980. State requested additional efficacy data submitted on April 7, 1981; new efficacy data submitted on June 23, 1981; product registered March 10, 1982.

Time Elapsed: 23 months.

(b) Boric acid: Application submitted to CDFA on August 28, 1981; no action as of May 21, 1982.

Time Elapsed: 9 months.

May 26, 1982: Letter received from CDFA for additional information to complete state registration of disinfectant toilet bowl cleaner even though product is presently registered by EPA. California asked for, among other things, eye and skin irritation studies on finished product. This is unreasonable since the product's labeling already contains the most stringent signal words: "DANGER/POISON". Testing would only substantiate that the same signal words should be used. Such testing would be duplicative and would serve no purpose.

Time Elapsed: 7 months.

June 1, 1982: "In our own case, on other pesticide products we manufacture, CDFA is asking new customers of ours to not only submit summaries but provide additional data. This is being requested of supplemental distributors who obviously do not have access to the data. . . . With respect to the four products mentioned in my . . . letter to (CDFA) the following status applies.

On June 1, 1982, I contacted our registration specialist at CDFA on the status of these applications. I was informed that they misplaced the data on two products and just found it and hence our applications were just entering the review stream.

It would be at least 90 days until we will hear about the registrations (which obviously puts us beyond the insecticide season and delays our ability to introduce new products until 1983.)

The sorrowful part in all of this is that a small company like ours suffers disproportionately vs. a large company that can afford legal counsel, lobbyists, delays, etc. while we depend on our own efforts and customer good will."

Time Elapsed: Open.

June 3, 1982: Company submitted a summary of products, and dates of application:

(a) Flying insect killer, submitted January 9, 1981.

Time Elapsed: 17 months.

(b) Home insecticide, submitted January 9, 1981.

Time Elapsed: 17 months.

(c) Home insecticide, submitted November 2, 1981.

Time Elapsed: 7 months.

(d) Patio, home and garden spray, submitted October 30, 1981.

Time Elapsed: 8 months.

"Each of these insecticides are formulas with active ingredients similar to those already sold in California. For each formula additional data have been requested from the base registrant and until the data have been submitted our application will not be processed. Our supppliers have indicated to us that much of the data requested is unnecessary and all data are additional to what is required for Federal registration."

June 4, 1982: (a) chlorinated sanitizer—application submitted to CDFA in December 1980; no request for data, no response to original application. Follow-up letter of December 16, 1981 elicited response on February 25, 1982 from CDFA indicating registration process had been delayed pending receipt of long-term toxicity studies. Finally registered: June 1982.

Time Elapsed: 18 months.

(b) Insect repellent: Application dated December 1980; data requested by CDFA in March 1982; still pending.

Time Elapsed: 18 months.

(c) Spray insecticide: Application dated December 1981; no written communication received as of June 1982; follow-up phone conversation advised applicant of a pending request for additional efficacy data. Company awaiting letter requesting data.

Time Elapsed: 7 months.

June 9, 1982: Company received request on May 26, 1982 from CDFA asking for efficacy data (against specific organisms) from 60-day shelf life samples, while only allowing 30 days in which to submit such data. "They (CDFA) have continuously made requests for efficacy and toxicity data rather than relying on the capabilities and integrity of the U.S. Environmental Protection Agency. This duplication of time and effort is a waste of resources in a department which appears to be both understaffed and mismanaged."

June 17, 1982: (a) CDFA requested additional data to support application to register an insecticide nearly one year after receipt of application. Not yet registered.

Time Elapsed: 12 months.

(b) Another insecticide, already registered by EPA, was pending in California for 14 months before CDFA requested additional data. Not yet registered.

Time Elapsed: 14 months.

(c) "The economic burden imposed by such delays is compounded where, as is often the case, the request for additional data has little merit."

These are but a few examples reported to CSMA by member companies of registration delays caused either by unnecessary, burdensome requests for generation of additional data or by failure of the state to process applications in a timely manner.

III. THE CALIFORNIA PROBLEM—HISTORY

The problems relating to the abuse of data generation requirements and registration delays are not new ones in the State of California. Since 1979, CSMA has attempted to work within the legal regulatory and legislative frameworks of the State to avoid the necessity for revisions in the federal statute. At a hearing held on September 5, 1979, by the CDFA concerning proposed changes in the state's pesticide regulations, CSMA warned that the regulation proposed by the state did not take into account the differences between pesticide uses. These comments also addressed the question of unnecessary or duplicative data requests. Unfortunately, CSMA was correct in its 1979 forecast in those comments that "the debate as to the authority under §24(a) of the states will increase and will culminate either in legal challenges or in additional attempts to amend the federal act if states impose requirements so contrary to those of the federal levels so as to make it impossible for manufacturers to market products on a regional or national basis."[1]

When California issued its final revised registration requirements in substantially the same form as originally proposed, the industry sought to obtain corrective legislation in the State legislature. These efforts, however, were unsuccessful and, subsequently, the industry filed suit in the U.S. District Court for the Eastern District of California (*NACA v. Rominger,* Civil No. S-80-85 MLS). This litigation has been stayed pending Congress' decision whether or not to amend this statute.

During all of this time, CSMA has continued to participate in administrative rulemaking procedures within the State to correct the registration deficiencies. California, meanwhile, has until recently refused to heed pleas from the regulated community for modifications in state registration procedures. Only after pressure generated by CSMA in the U.S. Congress has there been any attempt to even consider changes in the registration process. Yet the abuses continue and threaten to spread to other states.

Similarly, during the Congress' review of FIFRA over the past year and a half, CSMA has earnestly participated in developing compromise language for §24(a). California, on the other hand, has opposed any changes in FIFRA that might correct this problem.

IV. ACTIVITIES IN OTHER STATES

There is a very real concern that other states will move toward implementing similar procedures. A multiplicity of states implementing policies such as those in California would exponentially increase the burdens on the industry. We have already seen initiatives in several states that would increase unnecessarily the regulatory burden upon individual registrants seeking state registrations. In addition, there have been recent attempts by political subdivisions below the state level to regulate pesticides contrary to Congressional intent.

By way illustration, we are citing here a variety of attempts that have been made in different states to modify and broaden pesticide authority in ways that would result in unreasonable, unnecessary, unworkable, or duplicative regulatory burdens:

New York: Has attempted to require environmental impact statements prior to registration.

Massachusetts: Would require submission of duplicate EPA data or generation of additional data. Would permit political subdivisions of the state to regulate pesticides.

Maine: Has attempted a third category of restricted products.

West Virginia: Would require notification of adjacent land owners, including absentees, of pesticide application.

Oregon: Would extend pesticide regulatory authority to substate levels of government.

New Jersey: Consideration of a model ordinance which would permit cities, townships, etc. to require permits, posting of signs, notification of adjacent property owners and other restrictions prior to spraying of even household aerosol pesticide products.

V. HOUSE ACTION CONCERNING THE §24(A) AMENDMENT

For nearly a year and a half, CSMA has worked diligently to effect a change in §24(a) that would ensure timely processing of applications and reasonable data requests by states.

The basic provisions of §11 of H.R. 5203 which amend §24(a) of FIFRA evolved from House Agriculture Committee efforts to solve the registration delays and data issue and still maintain the state authority to regulate sale and use of pesticides. This amendment was reported out of the House Subcommittee on Department Operations, Research and Foreign Agriculture by a vote of 7-2. The full House Agriculture Committee approved H.R. 5203 by voice vote on May 6, 1982. Floor action in the House is pending on the bill.

Opponents of the amendment have attempted to categorize it as a state's rights or preemption issue. The fact of the matter is that the language currently contained in §24(a) of FIFRA would remain intact. States will continue to be able to regulate the sale or use of any federally registered pesticide or device in the state including the prohibition of any such product.

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[1] Statement of the Chemical Specialties Manufacturers Association before the State of California Department of Food and Agriculuture Concerning Proposed Changes in Regulations Pertaining to Economic Poisons, September 5, 1979, pp. 6-7.

VI. DISCUSSION OF THE SECTION 24(A) AMENDMENT PROVISION AS CONTAINED IN S. 2621

Mr. Chairman, we welcome this Committee's consideration of amendments to the Federal Insecticide, Fungicide and Rodenticide Act. FIFRA affects a large number of firms manufacturing, marketing, and distributing thousands of products defined as pesticides. We support this Committee's efforts and urge that S. 2620 and S. 2621 be combined and reported out to the full Senate for passage.

I should like to spend the remainder of my time discussing Senator Hayakawa's bill which further clarifies some of the basic provisions of the House amendment. This legislation, S. 2621, differs from H.R 5203 in the following areas:

(1) It clarifies that a state, but not political subdivisions thereof, may regulate sale or use of pesticides or require generation of data. While there is legislative history indicating a Congressional intent in this regard, the statute contains no express prohibition.

(2) It further refines the term "special local concern" to instances where the state obtains significant factual information which reasonably supports the conclusion that use of any pesticide or device within the state presents a concern relating either to an increased risk of any unreasonable adverse effects on the environment or reduced efficacy; and

(3) It extends the EPA review function to include special local concern data requests for agricultural products. As contained in the House bill, such review applied only to nonagricultural products.

CSMA believes that these refinements are both logical and desirable, and we urge this Committee to adopt Section 1 of S. 2621 in its entirety.

VII. SPECIFIC PROVISIONS OF SECTION 1 OF S. 2621

The bill recognizes that an overview is necessary to ensure that states' requests for generation of additional data in both the agricultural and nonagricultural areas are reasonable and not arbitrary or capricious. This safeguard is accomplished by virtue of an EPA review of additional data requests. Contrary to arguments in opposition to this approach, there are existing precedents in FIFRA for EPA review of state actions.

First, under the provisions § 24(c), a state is permitted to provide a registration for additional uses of federally registered pesticides for distribution and use within the state to meet special local needs. The EPA Administrator retains the authority to review these state registrations and disapprove them within a ninety-day period. The Administrator is given further authority to immediately disapprove any registration that is inconsistent with the Federal Food, Drug, and Cosmetic Act or if the pesticide represents "an imminent hazard."

Second, under § 27, dealing with State enforcement of state pesticide use regulations, the EPA may respond to a complaint referred to the state if the state has not appropriately responded to it within 30 days; thus the Administrator has the authority to oversee the enforcement actions of the state. In addition, if the Administrator determines that the State enforcement programs remain inadequate after appropriate notifications, the Administrator may "rescind, in whole or in part, the state's primary enforcement responsibility for pesticide use violations." Consequently, the Administrator was given the responsibility to review state enforcement actions and, if necessary, take over the state programs.

Third, under the provisions of § 18, the Administrator may "exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption."

Because in each of these precedents, an overview role may be exercised by the EPA Administrator, it is surprising that opponents have objected to incorporation of an EPA overview function in § 24(a). It is even more surprising when one considers the fact that the overviews required by §§ 24(c), 27, and 18 involve consideration of the merits of the state decision, including, always, scientific appraisal of the factual data and, often, risk-benefit evaluation, while the proposed EPA overview in the § 24(a) amendment requires no more than that the EPA Administrator determine if the state request for additional data is arbitrary or capricious.

The bill retains present state authority to regulate sale or use of pesticides and clarifies that such authority rests with states, but not with political subdivisions thereof. This provision is consistent with the legislative history of the 1972 amendments:

"* * * [I]t is the intent that section 24, by not providing any authority to political subdivisions and other local authorities of or in the States, should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides" (S. Rept. No. 92-8838 (Part II) 92d Cong., 2d Sess. 47 1972) Appendix E).

The limitation on substate authority to regulate pesticides was recognized in 1980 by the Attorney General of Massachusetts in disapproving proposed by-laws of the town of Wendell which attempted to regulate pesticides. In disapproving the by-laws, he concluded in part:

"The Federal Environmental Protection Agency in adopting regulations implementing the Federal act commented on the state agency administering the state plan as follows: 'It is not the intention of the Act or these regulations to authorize political subdivisions below the State level to further regulate pesticides. Federal Register, Vol. 40, No. 49, Wednesday, March 12, 1975, at page 11700. The comments pertained to 40 C.F.R. 171.7(a).'"

Similarly, in New York, ordinances adopted by a municipality regulating pesticides have been held invalid on the grounds that either the federal law or state law, which were not in harmony with the regulations, preempted the field. *Long Island Pest Control Association, Inc. et al* v. *The Town of Huntington,* 341 N.Y.S. 2d 93 (1973). Affirmed, 351 N.Y.S. 2d 945 (1974).

Senator Hayakawa's provision regarding political subdivisions would expressly incorporate this Congressional mandate into the statutory language of FIFRA and thereby preclude the necessity for further administrative review or litigation. This clarification, however, in no way precludes cooperation between the industry and local governments.

With respect to review by states of existing data or requests for generation of additional data, the bill sets forth the following standards:

(1) In the case of existing data previously submitted to EPA in support of a federal registration, the state may request the data from either the applicant or EPA, thereby resolving the data availability problem at the state level. If the state wishes to obtain the data directly from EPA, the registrants are afforded notice thereof.

(2) In the case of special local concerns pertaining either to an increased risk of any unreasonable adverse effect on the environment or reduced efficacy, the state may require additional data but must give the applicant written notice and justification for doing so. Special local concerns arise only when the state obtains significant factual information which reasonably supports the conclusion that the use of any pesticide or device within the state presents a concern relating either to an increased risk of any unreasonable adverse effects on the environment or a reduced efficacy.

Applicants wishing to contest the state's request for generation of additional data for either agricultural or nonagricultural products may submit the request to the EPA Administrator for review. In viewing the request, the Administrator may, on the basis that the request is arbitrary or capricious, overrule or modify the state request. Products in this category are not registered pending resolution of appropriate review.

In making requests for additional data beyond that requested by the Administrator, states are directed to take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk.

(3) A state's request for data which does not come within the realm of a special local concern data request is reviewable by EPA for both agricultural and nonagricultural products. EPA may disapprove a data request upon a finding by the Administrator that the request is arbitrary or capricious or that there is no reasonable basis for making use of the data in connection with a state's determination as to registration or approval of the pesticide. In general, products in this category are to be granted registrations pending further review.

Opponents have argued that the amendment would saddle EPA with numerous data reviews, would increase the Agency's administrative costs, would spawn litigation, and would create yet another layer of bureaucracy. These arguments do not hold up under careful scrutiny. EPA will not spend an inordinate amount of time sifting through state data requests.

The clarification as to when a special local concern may arise will have the effect of reducing the number of potential requests for EPA review since it is more objective and will serve to screen out unnecessary data requests.

With respect to special local concerns that pertain to nonagricultural products, such as a toilet bowl cleaner, it is very difficult to envision a local concern for such a product. But if one does exist, EPA would act merely to ensure that a data request is not arbitrary or capricious.

With respect to data requests not subject to a special local concern, this amendment will merely direct that the states have a reason for requesting the additional data.

We submit, therefore, that forecasts of numerous data reviews by EPA are greatly exaggerated. Where there are few data reviews, it follows there will be no major increase in the Agency's administrative costs, the number of lawsuits, or bureaucratic involvement.

One further point with regard to potential lawsuits involving EPA: the only time that a decision by EPA is reviewable in court is when that EPA decision overrules or modifies a state's special local concern data request. Such suit, it should be emphasized, can be initiated only by the state, not industry.

Inclusion of the requirement to make a distinction between agricultural and nonagricultural pesticides will assist in holding state requests for generation of new data only to appropriate uses (such as for agricultural uses) instead of imposing unnecessary across-the-board data requirements on the entire industry. Moreover, Congress has already imposed this requirement on EPA in § 25(a)(1) of FIFRA by directing the Administrator in prescribing regulations to "take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides." It certainly follows that the states should be held to the same standard.

The bill also imposes an obligation on the states to act upon most registration applications within 60 days of receipt or the product is deemed registered. When it pertains to a change in the use pattern or a new active ingredient, action must be taken within 120 days after receipt of the application and all data presently required by the state or, again, registration is deemed granted.

VIII. CONCLUSION

Mr. Chairman, CSMA appreciates this opportunity to comment on the Senate FIFRA legislation. We believe the best approach for the Committee is to combine S. 2620 and S. 2621 into a single bill and report it out to the full Senate for passage. The § 24(a) provision as it is in S. 2621 will go a long way toward assuring timeliness in processing applications and reasonableness in requests for additional data at the state level. We will be pleased to answer any questions.

Chemical Specialties Manufacturers Association,
Washington, D.C., July 15, 1982.

Hon. Jesse Helms,
Chairman, Senate Agriculture, Nutrition and Forestry Committee,
Russell Senate Office Building, Washington, D.C.

Dear Senator Helms: I am particularly pleased that you and the Senate committee on Agriculture, Nutrition and Forestry have recently held hearings on S. 2620 and S. 2621, proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). I am especially pleased that the morning of Tuesday, June 22nd, was devoted to concerns about Section 24(a) dealing with State authority.

I greatly appreciated the opportunity to testify before your committee, and welcomed the chance to respond to your questions, which I have enclosed for insertion in the permanent hearing record of the committee.

CSMA believes that the 24(a) language in S. 2621 will move toward eliminating the two basic problems that now exist, i.e., long registration delays and unnecessary data generation requests. Such excessive state regulations will increasingly impose economic hardships upon the pesticide industry and deprive consumers of safe and effective pesticides needed to control pests which disrupt our economy and reduce the quality of our lives. While this language leaves intact the States' authority to regulate the sale or use of a pesticide, it also establishes an orderly procedure for reasonable data requests and timely registration by the States.

We at CSMA would respectfully urge you and the committee to proceed to markup S. 2620 and S. 2621, combining these two much needed bills. Again, thank you for your interest and concern about this important matter.

Sincerely,

Ralph Engel,
President.

Enclosure.

Question 1. One puzzling factor in connection with the problems your industry has had with the California registration program, namely the delay in processing applications and the additional data requests, is the absence of lawsuits.

What is your explanation for this?

Why haven't your members taken these problems to the courts?

Answer. The problems relating to the abuse of data generation requirements and registration delays are not new ones in California. Since 1979, CSMA has attempted to work within the legal, regulatory and legislative frameworks of the State to avoid the necessity for revisions in the federal statute.

When California issued its final revised registration requirements in substantially the same form as originally proposed, the industry sought to obtain corrective legislation in the State legislature. These efforts, however, were unsuccessful given the States' administration policies. Subsequently, the industry filed suit in the U.S. District Court for the Eastern District of California (Civil No. S-80-85 MLS) to enjoin implementation of these regulations. The injunction was denied. To file suit on the merits of each individual application for registration is unworkable and would place a tremendous economic burden on many small companies. In the absence of any federal standards, if each registrant in a number of States were required to file suit each time the States imposed arbitrary or capricious registration practices, the court dockets would be unreasonably burdened as well. Litigation is therefore not the proper solution.

CSMA instead has sought legislative changes in FIFRA to correct a wrong that is imposing a substantial economic burden on the industry and threatens to grow beyond the boundaries of the State of California. We have already seen initiatives in several States that could impose arbitrary or capricious or duplicative regulatory burdens upon registrants. Interstate commerce will be severely affected through such a process and the public will be denied use of necessary products because of these efforts.

We believe that Congress can provide a reasonable solution by amending Section 24(a) and by providing a workable procedure and standards that both registrants and the States can follow when additional data requirements are in question. These are embodied in S2621 presently.

Question 2. Along this same line of thought, if S. 2621 is adopted, just how often do you anticipate your member companies and others seeking States registrations will appeal State data requests to EPA?

How often do you expect that court review will be sought?

Answer. The intent of the section 24(a) amendment is to prevent arbitrary or capricious data requests by the States. S. 2621 provides a procedure and standards by which such requests would be made. Consequently, a state would not make across the board data requests or demand data prior to registration simply because "it would be nice to know" or require data unrelated to a products use or demand data for non-substantive registration changes as a brand name or company name change. With these and other instances of abuse reduced or eliminated, state data requests should be directed toward legitimate local concerns. The industry can and will address and respond to these concerns. Appeals to EPA should therefore be minimal. S. 2621 does not permit a registrant to seek federal court review of an EPA decision regarding a special local concern data request. Only a state, if EPA overrules the state's request for data on the basis of it being arbitrary or capricious, can appeal for federal court review. A registrant could seek state court review, but if a state had been upheld by EPA it is highly unlikely that a registrant would pursue this matter in the state courts. Court review should therefore only occur in rare instances. In regard to data pertaining to a special local concern, the decision of EPA is final and not subject to judicial review.

Question 3. Relatively speaking, what portion of the additional data requests by California is the result of some special local concern and what portion is made for other reasons?

Answer. Unfortunately some 80 to 85% of applications for registration have been affected by the State of California's policy requiring the development of new data and additional review of existing data on the same products already registered by EPA and most other states. In requesting such additional data, the state, for the most part, does not make clear what prompts its request. In many cases, the state has held the application for more than one year before even asking for additional data. This non-selective, across the board approach has been the rule and has resulted in competition being stymied. Manufacturers have been prevented from getting safe and effective products on the market—they are virtually locked out of the California marketplace.

Based upon my latest estimate, I would say that additional data requests made as the result of some special local concern are insignificant as they relate to the overall number of applications submitted.

Question 4. Please cite some examples, assuming that S. 2621 is adopted of the following:

a. What would you consider to be a special local concern;

b. What types of request do you believe would not be permitted under the new section 24(a)(2)(C);

c. What type of information would a State need to have to meet the requirements to assert a special local concern; and

d. What would you consider to be sources of comparable data available to a State for purposes of satisfying a request for additional data.

Answer. a. We would concur with the definition as set out in S. 2621 specifying that a "special local concern" relates to instances where the state obtains significant factual information which reasonably supports the conclusion that use of any pesticide or devise within the state presents a concern relating either to an increased risk of any unreasonable adverse effects on the environment or reduced efficacy. To this end a special local concern could be determined where a crop is grown in a portion of the state that has particular climatic and edaphic conditions resulting in higher residue levels than expected.

b. Where one company purchases the products of another already registered Federally within that state and submits an application to change the name of the registrant.

In the absesnce of a special local concern the request for additional data that would duplicate data already submitted to EPA in support of a Federal registration should not be requested by the State.

c. The main benefit of the 24(a) amendment would be to eliminate unreasonable data requests such as described in the preceding answer. Therefore, data requests based on special local concern should become more evident. Adverse information specific to a state regarding health or efficacy that is based on objective reality should meet the requirements to assert a data request under the special local concern provision.

d. As pesticides require federal registration by EPA prior to state registration, data already submitted to EPA that provides information appropriate to the state concern would be comparable data. Additionally, other sources of comparable data are: other states, foreign governments, other federal agencies, in some cases other companies who may be the primary registrant or who may have developed data on the product in questions. The open literature could contain relevant data. Finally, the registrant may have comparable data developed in regard to a like concern or for another purpose but responsive to the question.

STATEMENT OF HON. JOHN M. STACKHOUSE, DIRECTOR, OHIO DEPARTMENT OF AGRICULTURE, ON BEHALF OF THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE

Mr. Chairman and members of this distinguished Committee: I am John M. Stackhouse, Director of Agriculture, of the Ohio Department of Agriculture, and I have the privilege today to speak on behalf of the National Association of State Departments of Agriculture.

We, the administrators of State departments of agriculture, are charged with the responsibility for implementing State laws relating to regulation of the sale and use of pesticides. In addition, under the provisions for "State primacy in pesticide use enforcement," we have assumed the major enforcement role in ensuring that pesticides are used safely and effectively in this country, within the statutory provisions of FIFRA.

The ten years since FIFRA was extensively amended in 1972 have been extremely difficult for both EPA and the States.

Since 1972, we have made slow but steady progress in implementing an almost totally new system of pesticide registration, one in which EPA is assigned primacy, with the States authorized a complementary role under Sec. 24. The States have made strenuous efforts, sometimes under difficult circumstances, to develop a true partnership with EPA; and the record shows that we have worked on behalf of pesticide users and the general public to remove unnecessary regulatory burdens and make the system more efficient, more flexible and more responsive.

Thanks in part to our efforts, the entire pesticide regulatory process is now developing a forward momentum which, if interrupted for any reason, would be costly to agriculture, industry and the American public. We, as regulators and administrators, are therefore vitally concerned that any changes in FIFRA preserve the progress we have achieved with great difficulty during the past decade.

I will focus my remarks this morning on a proposed amendment to FIFRA Section 24(a) that would seriously jeopardized the integrity of State regulatory programs. This proposal, contained in Sen. Hayakawa's bill S. 2621, would require EPA to become deeply entangled in the process of determining what data a State may request in the course of reviewing a product submitted for registration within that State.

Specifically, the proposed amendment affects a State's authority to require pesticide firms to supply additional health or safety data beyond that required by EPA. State authorities could, under the proposal, require pesticide firms seeking a State registration to submit data in addition to that previously given to EPA. However if the pesticide firm chooses to challenge the request, the EPA administrator must assume the role of referee and attempt to decide whether or not the request is "arbitrary or capricious." In most cases this would likely involve a time-consuming review of the specific factors and local considerations that caused the State administrator to issue the data request.

If the EPA administrator determines that the request is reasonable and appropriate, his decision is subject to judicial review. If, on the other hand, he decides that the State request is "arbitrary or capricious," he must overrule or modify the request. States could then apeal the EPA ruling in Federal court, but only in cases where a State can demonstrate "special local concerns."

In addition, the bill sets time limits on the period in which States must act to approve or deny pesticide registration or re-registration applications.

At the present time, Sec. 24(a) consists of a single sentence. Its meaning is clear and unambiguous: "A state may regulate the sale or use of any Federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act."

The proposed amendment, on the other hand, would replace this simple sentence with 165 lines of highly convoluted language subject to ambiguities and legal pitfalls. The provisions for judicial review alone will increase the amount of FIFRA litigation that is already clogging the Federal courts. The cost of this litigation is ultimately passed back to pesticide users in the form of higher prices.

The proposed amendment will also require each State to draft new regulations and establish new regulatory procedures that will be more cumbersome and time-consuming than the very simple and inexpensive procedures now operative in most States. This regulatory change will mean higher registration fees which, in turn, will be passed back to consumers.

Moreover, the 60-day and 120-day timetables spelled-out in S. 2621 mandate some form of conditional or temporary registration procedure at the State level. Ohio State law does not now permit the issuance of conditional registrations, nor, to my knowledge, do the pesticide statutes in most other States. State laws would have to be brought into conformity with this new requirement.

Finally, the proposed amendment puts EPA in the difficult position of having to referee between States and the industry and intrude into a decisionmaking process that exclusively involves State and local health and safety considerations. This time-consuming responsibility will divert agency resources from the far more important task of expediting the Federal registration and re-registration programs.

Mr. Chairman, our Association questions the need for amending Sec. 24(a). In general, the States have made every effort to carry out their regulatory responsibilities under Sec. 24(a) in a flexible, expeditious, and responsible manner. We have worked closely with the Congress, EPA, chemical industry, formulators, pesticide users, and other affected interests to minimize regulatory burdens and keep the cost of our programs at a bare minimum, while at the same time protecting the health and safety of all people.

In recent years, a serious conflict has developed in California. We frankly acknowledge this problem but believe it can be resolved within the framework of existing law. The record shows that Sec. 24(a) has operated successfully in 49 States since its enactment in 1972. Consequently, the proposed amendment penalizes 49 States that have faithfully carried out Congress' mandate in order to solve a problem that exists in only one State.

The industry has charged that there are threats of similar actions in six other States. It has been said that there is the potential within the State pesticide programs to create 50 "mini-Epa's" throughout the nation. Mr. Chairman and members of this Committee, it is my firm belief, as a Director of Agriculture for 16 years, and having served four years here in Washington as an official of the chemical industry, and having had a direct role in the writing of FIFRA in 1972, that there is not a threat as charged by the industry and others toward the States' massive usurpation of powers extended under the legislation that was enacted in 1972. It has been charged that, "California and six other States have attempted to expand their pesticide programs to exceed or duplicate the Federal registration requirements." To the best of my knowledge, California is the only State that issues additional data requests on a routine basis. Mr. Chairman, I submit to you that we cannot begin to legislate on probability; and Mr. Chairman, I submit to you that we cannot begin to legislate at the national level to correct a problem that can be corrected administratively within one State. If that be the case, there are probably hundreds of other issues under FIFRA that could be brought to the Congress and log-jam thin legislation for years.

I might add that efforts are now underway in California to resolve differences between the State and industry to minimize, where possible, the adverse effects on industry of California pesticide regulations.

NASDA fully recognizes the potential burden on the pesticide industry if States began to issue excessive and unnecessary data requests. In a policy resolution (No. PI-17) adopted last September at our annual meeting, NASDA recognized that Congress has set minimum standards for the regulation of pesticides and that such minimum standards meet the specific needs and expectations of each and every state. We further resolved to work with all affected parties toward solving any future problems relating to requests for data by States. A copy of the resolution, which was approved unanimously, is attached to my testimony, and I respectfully ask that it be made a part of the permanent hearing record.

Perhaps the strongest argument I can offer in support of our position of no change in Sec. 24(a) relates to the historic rights of the States to manage their own affairs in a responsible manner. Federal preemption has become an all-to-frequent remedy when problems arise at the State level. Consequently, we in the states have witnessed a gradual but serious erosion of responsibilities traditionally exercised by State governments. The proposed amendment to Sec. 24(a) may be viewed by some as a very minor expansion of Federal power at the expense of the States, but it contributes to a trend that has already gone too far.

Section 24(a) strikes a sound and workable balance between States rights and the legitimate authority of the Federal government to set national pesticide policy. State departments of agriculture respectfully request your help in protecting State pesticide programs by opposing any changes to Sec. 24(a).

Mr. Chairman, I appreciate the opportunity of providing this statement on behalf of our Association and would be happy to respond to any questions you may have.

OHIO DEPARTMENT OF AGRICULTURE,
Columbus, Ohio, July 1, 1982.

Hon. S. I. HAYAKAWA,
Dirksen Senate Office Building,
Washington, D.C.

DEAR SENATOR HAYAKAWA: I am enclosing a copy of my responses to your questions which were provided to me during the hearing on proposed amendments to FIFRA held before the Senate Committee on Agriculture, Nutrition, and Forestry, June 22, 1982.

I am impressed by the careful consideration which you and other members of the Committee are giving to proposed amendments to Section 24 of FIFRA. You will note by my responses to your questions that I am encouraging you to consider other means of correcting existing or potential problems rather than amending Section 24(a).

I fully appreciate the opportunity to present my testimony on behalf of the National Association of State Departments of Agriculture and to respond to your written questions.

If I can provide additional information and comments, please let me know.

Sincerely,

JOHN M. STACKHOUSE, *Director.*

Enclosure.

Question. Time and time again, we have heard complaints from pesticide manufacturing firms about the registration problems with the State of California. These complaints generally revolve around time delays and excessive data requirements.

Does this indicate to you that California is simply doing a more thorough a more complete job in registering pesticides? And if so, what does this say about the other

States? Are they being lax, exposing their citizens to unreasonable risk or doing a less than adequate job?

Answer. I do not believe that other states are doing less than an adequate job in protecting their citizens from unreasonable risk. Ohio and other states are relying on the requirements and processes used by federal EPA in registering pesticides and have found this adequate except in cases of emergency (Sec. 18) and local need (24c). Section 24(a) deals only with providing states with authority to regulate the sale or use of any federally registered pesticide. Your statement of the issue is registration which can best be resolved by amending Sec. 3 rather than Sec. 24(a) which does not include registration.

Question. The State of Ohio has not adopted the same policies of California in making additional data requests on almost all registration applications. Do you think that you in Ohio are adequately protecting the health and safety of your citizens without requiring all the data that California is asking for?

Answer. I am fully convinced that Ohio is adequately protecting the health and safety of Ohio citizens without requiring additional data. We depend on USEPA to fulfill its responsibilities under FIFRA in registering pesticides and overseeing the proper use of these pesticides which I believe follows the Congressional intent of FIFRA. Also, Ohio does not have the wide variety of crops and varied growing conditions which exist in California. Lack of significant health problems related to pesticide useage in Ohio would indicate that we are doing an adequate job.

Question. Your statement expresses grave concern about EPA overview of State requests for additional data. Is not the EPA overview in section 24(a) consistent with the Administrator's overview in sections 24(c), 27, and 18?

Answer. The suggested EPA overview in Sec. 24(a) is comparable but not necessarily consistent with the Administrator's overview in Sec. 24(c), 27, and 18. The proposed amendments to Sec. 24(a) places restrictions on the state's overall ability to regulate the sale or use of a pesticide while the other sections are specific to additional registrations, emergencies, and enforcement.

Question. Does not the EPA overview in section 24(a) requiring a decision that a State request is only arbitrary and capricious—represent a less stringent authority than the ability to cancel a State registration under section 24(c) or a State enforcement program under section 27?

Answer. Yes, but this proposal along with other amendments pre-empts the state's authority to regulate the sale or use of a federally registered pesticide. As stated previously, it is my firm conviction that problems with registration should be dealt with in Sec. 3 rather than by amending Sec. 24(a).

Mr. Stackhouse, on September 4th, 1981 before the House subcommittee dealing with FIFRA, you made the following statement:

"NASDA recognizes the potential undue burden which would be placed on industry if a number of States should routinely require the submission of full data to support the state registration of an EPA-registered pesticide product. However, this problem now exists with only a very few states and there is every indication at this time that the majority of states have no intention of implementing such a requirement for data submission."

Question. Can we interpret this statement to mean that if a majority of States begin requiring full data submission then we should look at doing something on the Federal level to curb such activiity?

Answer. This may be a reasonable interpretation but such action should not be taken on the basis of probability. At present, a very limited number of requests, with the exception of one state, for full data to support state registration have been made. If such action should become necessary, consideration should be given to amend Sec. 3 rather than 24(a) which deals only with regulating the sale and use of pesticides.

Question. While you have recognized that "a problem exists in California", if section 24 as I have proposed, went into effect could your members live with it or do you feel the health and safety of the environment would be jeopardized because of the passage?

Answer. Your proposed amendment to Sec. 24(a) would jeopardize the authority of states to regulate the sale or use of pesticides within the states. As I understand the problem in California, it applies to withholding state registration as a means of regulating sale and use of pesticides. Other methods of state regulation are available other than withholding registration. If my understanding is correct, then registration problems should be corrected under Sec. 3 rather than by imposing costly, time consuming and potentially difficult legal procedures which will hamper overall state regulation of pesticides.

I do not believe the health and safety of the environment would be jeopardized if your proposal is enacted, but I would urge that consideration be given to my recommendation that the problem can best be corrected by amending Sec. 3 rather than imposing the proposed restrictions by amending Sec. 24(a).

OHIO DEPARTMENT OF AGRICULTURE,
Columbus, Ohio, July 1, 1982.

Hon. JESSE A. HELMS,
Dirksen Senate Office Building,
Washington, D.C.

DEAR SENATOR HELMS: I am enclosing a copy of my responses to your questions which were provided to me during the hearing on proposed amendents to FIFRA held before the Senate Committee on Agriculture, Nutrition, and Forestry, June 22, 1982.

I am impressed by the careful consideration which you and other members of the Committee are giving to proposed amendments to Section 24 of FIFRA. You will note by my response to your questions that I am encouraging you to consider other means of correcting existing or potential problems rather than amending Section 24(a).

I fully appreciate the opportunity to present my testimony on behalf of the National Association of State Departments of Agriculture and to respond to your written questions.

If I can provide additional information and comments, please let me know.

Sincerely,

JOHN M. STACKHOUSE, *Director.*

Enclosure.

Question. Mr. Stackhouse, specifically what is it about S. 2621 that you feel the State regulatory agencies just cannot live with?

Answer. The entire authority for state pesticide programs rests with Section 24(a) of FIFRA. Specifically, this gives authority to States to control the sale and use of pesticides within the State. The issue with the State regulatory agencies is "Do we need state pesticide regulatory programs?." We feel strongly that the CSMA amendment to Section 24(a) will in effect provide federal pre-emption of state pesticide regulatory programs.

I believe the Committee needs to consider "What purpose do State programs serve?". In my opinion, pesticide regulation by State Departments of Agriculture has been very effective in providing service to pesticide users and the general public by working to provide efficient regulation of usage while still maintaining the safety and welfare of the people. While the chemical companies are concerned over problems involved with pesticide registration in California, I would call to the Committee's attention the fact that pesticide regulation by the California Department of Food and Agriculture has allowed for the continued use of most pesticides in California.

As I understand, the problem appears to be the refusal of California to register certain pesticide products without submission of additional data beyond what has been required by US EPA for registration. As far as I know, there is no federal requirement for states to register pesticides. However, I believe all state programs except one embody this feature. I feel that registration of pesticides was essentially pre-empted by the Federal Government in 1972 by the enactment of FIFRA.

However, the States were given permission to regulate the sale or use of pesticides in their respective State. I feel that the registration of pesticides is a separate procedure from controlling the sale and use of pesticides. Admittedly, California is using registration as a method of controlling the sale and use of pesticides. I believe that other methods should be used rather than registration.

I am concerned that in the manner this issue has been presented the Committee has not been provided with a clear picture of the impact that S. 2621 will have upon the State's authority to regulate the sale and use of pesticides. If what is intended is for total federal pre-emption of pesticide regulation, then it would seem the CSMA amendments are appropriate. However, if the issue is only to clarify the registration procedure, it seems to me to be much more appropriate to amend Section 3 rather than to do anything to weaken or to complicate the intent of Section 24.

Question. Do you feel that it is unreasonable to require that a reason be given whenever additional data is requested?

Answer. No. Such a request should indicate the purpose as well as fully justify the need for additional data.

Question. Is this not the normal practice in most States already?

Answer. Yes. In Ohio we have only made requests for additional data in meeting the provisions in Sec. 24(C).

Question. How about the EPA review of such requests on petition of an applicant? Is this the major problem?

Answer. Yes. Presently, the states have the authority to control the sale and use of pesticides within the state without review by USEPA as authorized in Sec. 24(a). State laws are written to provide this authority. S. 2621 as proposed would pre-empt the states authority to regulate the sale and use of pesticides in that state by such a review which is contrary to present state laws.

Question. The EPA decision is subject to judicial review. Don't you believe that that will help insure that EPA will make careful determination in any of these cases?

Answer. Normally yes, but consideration should be given to situations which are abnormal. For instance, the majority of the scientific community, I believe, feels the administrator made an "arbitrary and capricious" decision when many uses of 2,4,5-T were cancelled.

The issue is the states authority to regulate the sale or use of a federally registered pesticide which should not be confounded with and has nothing to do with the required registration of pesticides by USEPA which is a separate process.

Question. Since the standard of review for data requests relating to special local concerns is that EPA must find that the State acted in an arbitrary and capricious manner; just how often do you think an applicant will win one of these appeals?

Answer. Seldom, if ever. I cannot conceive of any responsible state official or state acting in an arbitrary and capricious manner. Yet, this proposed judicial review can result in costly, long long delays which will utilize extensive staff time though an applicant may not win the appeal.

Question. EPA could also reject a State request if comparable data is available elsewhere. What do you consider to be comparable data?

Answer. Data involving similar crops, hosts, climate, soils, growing conditions and other variables which can best be determined within states based on special concerns.

Question. What about the provision relating to requests that do not involve a special local concern? In your opinion how much of the data that a State may request would fall in this category?

Answer. Very few or no requests for additional data that do not involve a special local concern would fall in this category, and only when the request is fully justified based on conditions existing within a state which require special consideration.

Question. Is this provision particularly troubling to you?

Answer. No, as far as registration goes but I have concern regarding what is meant by approval. To my knowledge, Ohio has not requested such additional data. However, it appears that this provision is more suitable under registration of pesticides rather than under Sec. 24(a).

Question. One last area of inquiry is the time limitations. Do you think that 60 days to process an application for a general use, non-agricultural pesticide is reasonable? Are there any time limitations under Ohio law? Isn't 120 days to process a restricted use or an agricultural pesticide application sufficient to accommodate most situations? Other than dropping them entirely, do you have any suggestions as to how the time limitations could be changed to make them more acceptable to You?

Answer. In general, I feel the time limits suggested seem reasonable but I really have no basis to suggest alternatives. Ohio does not have a time limit stipulation in its law. If time limits are necessary, provision should be made for extensions to cover exceptions or unexpected difficulties.

Question. If each State begins to ask for additional data over and above that required by EPA, and each State could ask for different kinds of data which could be very costly, what do you feel the result would be to farmers and the companies? I mean, could companies do all this work and maintain the same product cost to the farmer? With the exception of California, can you give me any examples of other States where additional data is regularly requested?

Answer. Obviously if each State requested different kinds of data on a regular basis the costs to the farmer would increase. Presently very few requests have been made by States except for California.

Question. Have you ever needed such data in Ohio? How often are such requests made? Can you cite a specific example?

Answer. Ohio has requested additional data because of incompleteness on 2 or 3 occasions in the last five years when registering pesticides under 24(c) only.

Question. Do you know of any State that requests copies of all the data reviewed by EPA? How about summaries of the data submitted to EPA?

Answer. I am not aware of any State, with the possible exception of California, that requests copies of all data reviewed by EPA or requests summaries of the data submitted to EPA.

STATEMENT OF BRUCE HAWLEY, ASSISTANT DIRECTOR, WASHINGTON OFFICE, AMERICAN FARM BUREAU FEDERATION

The American Farm Bureau Federation is a general farm organization representing farmers and ranchers in 48 states and Puerto Rico. Farm Bureau membership exceeds three million member families. Farm Bureau members account for over 75 percent of all agricultural chemical use. Farm Bureau members buy, store, and apply pesticides; have front-line exposure to whatever risks are involved in chemical handling and use; and expect the federal government to fulfill its responsibility of evaluating pesticide safety and effectiveness. The Environmental Protection Agency has not to date fulfilled this statutory obligation.

The 1947 passage of FIFRA brought all pesticides that move in intrastate commerce under federal regulation, requiring a registration process to determine whether the products were safe and effective. USDA operated the program. In 1970, pesticide responsibility was administratively transferred to the Environmental Protection Agency.

1972 amendments to FIFRA expanded the requirements for environmental and safety data necessary to support a registration, made misuse of a pesticide illegal, required more hazardous products to be classified for restricted use, and authorized a training program whereby applicators could become certified.

Domestic usage of pesticides is now approximately 1 and a half billion pounds a year. Agricultural and forestry use accounts for 72 percent of that amount. Of the remainder, 21 percent of use is industrial, commerical, and governmental; and 7 percent is home and garden. Despite the magnitude of agricultural use, over 85 percent of all reported pesticide related injuries, illnesses and fatalities occur in urban/suburban areas.

There is currently a rapid change, almost a revolution, of technology being made in agricultural crop planting techniques in several major production regions in the United States. This change involves a movement from conventional tillage methods to conservation tillage, either minimum-till or no-till production methods. This change is causing dramatic reductions in soil erosion problems. Use of conservation tillage technology is reducing soil erosion by 50 to 90 percent over conventional tillage methods. Additional benefits of conservation tillage include additional wildlife habitat because of the year 'round presence of crop residue on the surface of the soil, and reductions in surface water runoff.

Less than a decade ago, it took six weeks of heavy equipment operation to put in the crop in the corn belt. Five years ago, about 23 percent of the corn belt used "conservation" tillage. Today, 46 percent of the land receives such treatment. Because of the increased reliance on minimum-till or no-till planting techniques, farmers are able to plant 90 percent of the acreage in the corn belt area in only ten days. This revolution will produce dramatic results in terms of environmental improvements and production potential. One of the keys to the success of this movement will be continued access to necessary tools of production, particularly herbicides and insecticides.

Although there are over 1,200 active ingredients currently registered, over 90 percent of the agricultural poundage used involves only 150 active ingredients. Nearly all of "agriculture's 150" still carry the registrations issued by USDA prior to 1970. For a variety of reasons, the Environmental Protection Agency has failed to carry out the re registration process mandated by the 1972 FIFRA. They have failed to classify pesticides for restricted or general use according to the product's environmental or human health hazard; and, according to EPA testimony only last year, EPA estimates it may take as much as 40 years to complete this re-registration job. We urge this Committee to report amendments to FIFRA that will expedite the ability of the Environmental Protection Agency to register pesticides so that producers might have a clear understanding of what chemicals are, and will continue to be, available for use in production agriculture.

Four years ago, the Environmental Protection Agency testified before Congress that the population of the United States was facing a cancer epidemic, in part related to the use of pesticides. As the facts have become available, it has been shown that cancer in man has been decreasing for the past thirty years with the exception of lung cancer. Clearly, the predicted threat of a cancer epidemic, obviously used for political purposes to prod Congress into passage of comprehensive environmental legislation, never materialized.

Two years ago, the Environmental Protection Agency, in response to a study suggesting that there were increased incidents of spontaneous miscarriages associated with the environmenal release of 2,4,5-T for forestry uses, moved to suspend most major uses of that pesticide. That study was so flawed that even the Environmental Protection Agency backed away from it as being without foundation and without credit.

Last year, the governor of California, in what was a blatant political move, refused to allow the use of modern technology to control an outbreak of the Mediterranean fruit fly that had the potential of devastation for agriculture--not just in California, but throughout the southern fruit and vegetable belt of the United States. Only as a result of intervention by the federal government, was that problem nipped before it became totally uncontrollable.

Opponents of pesticide use now argue that farmers do not need pesticides anyway--organic farming is supposedly the answer. The suggestion flys in the face of scientific fact that has shown one dollar's use of pesticide returns ten dollars of increased agricultural production.

Our purpose is not to suggest that pesticide use is without risk or without need of appropriate regulation or continued oversight. Our purpose is to suggest only that pesticides in today's agricultural production system are a necessary component that has aided in producing a bounty of safe food in this country unmatched by any other in the world.

We are sure this Committee will be flooded with all the old argu-ments against pesticides, and several new ones. We urge you to avoid being diverted from the fundamental obligation of FIFRA--to assure that pesticides are safe and effective if used according to the label. We urge you to resist those that would turn FIFRA into a social tool or a "lawyers relief" act.

We encourage this Committee to move ahead with legislation that will expedite the ability of the Environmental Protection Agency to complete its statutorily mandated task of reviewing pesticides to determine whether they are safe and effective. The single largest stumbling block to the proper execution of this task to date appears to be the congressional and administrative inability to resolve the issue of how to deal with the "compensation for data" issue. We commend the Chairman for proposing amendments to the pesticide law that would amend Section 3 in an effort to resolve this issue. We are not a registrant of pesticides and have no proprietary interest in any product; as such, our interest in this section is only to assure that it is amended in a manner that would provide its smooth operation upon implementation by the Environmental Protection Agency.

Some have expressed concern that these amendments might decrease the competitive nature among industry with relation to pesticide marketing and production. We are not convinced that these amendments would cause a substantive decrease in competition among the industry. However, even if that should be the case, we believe it is in the best interest of our members, the farmers and ranchers of this country, to run some risk of loss of competitiveness within the chemical industry in exchange for a system that will afford manufacturers the protection necessary to provide an adequate incentive to keep them in the research and development process--a process so vital to the development, marketing and availability of new pesticide products to meet the ever changing demands of the future for pest control in agriculture.

In testimony before this Committee, others have suggested the inclusion of a "right to sue" provision. Under such a provision, any person aggrieved by another's use of pesticides could file suit in a federal district court seeking equitable relief. Farm Bureau strenuously opposes such a proposal. Any person whose health, safety or property is jeopardized by another's action, including the use of pesticides, currently has access to legal and equitable remedies in state or federal courts for redress. We are aware of no situation where any individual who is threatened or harmed by another's actions is not able under existing law to seek appropriate relief. Also the phrase "aggreieved person" contemplates an indeterminable class of potential plaintiffs who need not suffer actual or potential injury to claim standing.

Further, we believe that the "right to sue" provision would be subject to great abuse. Such a provision could be used to obtain injunctions against the use of pesticides even though the product was used in a manner approved by EPA and the states. The provision could be used to stop application of pesticides in public health programs, emergency applications to control insect infestations, and to stop individual farmers' applications even at a time when a two-

or three-day delay in a pest control program might spell the critical difference between saving and losing a farmer's investment in that entire crop production year.

Finally, we believe that such a provision could result in literally hundreds of enforcement suits that could be brought by private persons which could be inconsistent with and interfere with enforcement actions and policies of the states and the federal EPA. In short, such a provision would enable every person in the country who chooses to file such a suit to set himself up as a private "attorney general", interpreting the federal statute for purposes of initiating litigation in the federal district court. The provision could result in the choking of already over burdened federal district courts, and in particular the federal district court for the District of Columbia, with what would frequently be no more than nuisance suits. We do not believe that the technical and scientific issues associated with making intelligent regulatory decisions on pesticide use will benefit from that kind of exhaustive litigation. We urge rejection of such proposals.

Senator Hayakawa has offered an amendment that attempts to address the delicate balance between a state's right to issue regulations and regulate the use of pesticides within the state and federal preemption or federal responsibility to expedite the registration and availability of safe and effective chemicals. We believe that the Senator has done a responsible job of treading that narrow line between preempting state authority and precluding state excess of regulation. We applaud the Senator's efforts and support his amendment.

In summary, we believe the bills offered by Senator Helms and Senator Hayakawa, taken together, constitute a responsible package to improve current FIFRA law. We urge this Committee's acceptance of those provisions and their reporting of them without further amendment.

I would be happy to respond to any questions.

American Farm Bureau Federation,
Washington, D.C., June 23, 1982.

Hon. S. I. **Hayakawa,**
Committee on Agriculture, Nutrition, and Forestry, Russell Senate Office Building, U.S. Senate, Washington, D.C.

Dear Senator Hayakawa: During hearings before the Senate Committee on Agriculture, Nutrition, and Forestry, one of the witnesses, Jay Feldman, representing "The Coalition Against the Misuse of Pesticides" testified that pesticides are a significant cause of cancer in agricultural workers and farmers.

Mr. Feldman cited a University of Iowa study in support of this contention. I am enclosing for your information, and request inclusion in the record, a summary of that University of Iowa study. I call to your attention several of the conclusions made by the researchers as they evaluated this important subject. Perhaps of most significance, overall cancer death rates among Iowa farmers are a bit lower than the mortality rate among non-farmers.

We hope that this information will be helpful in assisting the Committee in correcting the misrepresentations contained in the statements made by Mr. Feldman during his testimony.

We thank you for consideration of these additional comments by the Farm Bureau.

Sincerely,

Bruce Hawley,
Assistant Director, Washington Office.

THE UNIVERSITY OF IOWA HEALTH NEWS SERVICE—STUDY POINTS TO CANCER RISKS ON IOWA FARMS

(By Kay Brief)

Iowa City, Iowa.—Death rates from six cancers are disproportionately high among farmers, shows a recently completed Univerity of Iowa study.

Compared to nonfarmers, age-adjusted mortality rates among farmers are 78 percent higher for prostatic cancer, three times higher for lip cancer, twice as high for multiple myeloma (a bone marrow cancer), 77 percent higher for leukemia, 60 percent higher for stomach cancer, and 58 percent higher for lymphatic cancer.

The researchers analyzed the 1971–1978 death certificates of 20,311 white males. Analysis was limited to white males due to few nonwhite farmers in Iowa and incomplete occupational data for women.

"We do think these cancer mortality rates are occupationally oriented," says Dr. Leon Burmeister, U of I associate professor of preventive medicine and environmental health.

"Researchers in other countries and states have also found risks of certain cancers higher among farmers," he continued. "Ours is the only large-scale study in the Midwest, an area where farmers constitute a relatively large occupational group."

The current study supports trends spotted in Burmeister's 1964–1970 study of Iowa cancer deaths.

The only cancer mortality rates which are disproportinately high among nonfarmers are the smoking-related cancers (mouth, buccal, esophagus, respiratory cancers). Lung cancer mortality rate is 23 percent higher among nonfarmers than farmers.

Overall, cancer death rates among Iowa farmers are a bit lower than the mortality rate among nonfarmers, due to this lower rate of smoking-related cancers among farmers.

Burmeister believes the reason for this lower rate is that farmers smoke less.

"Smoking is inconvenient and hazardous for farmers due to the constant presence of animals, chemicals and flammable materials such as hay," continues the researcher and former farm boy.

"If you eliminate the smoking-related cancers from the comparison, the cancer death rate would be much higher among Iowa farmers than nonfarmers," continued Burmeister.

For 1971–1978, the age-adjusted mortality rates are based on the number of deaths for every 100,000 white males over age 20:

Prostatic cancer rate is 206.48 deaths among farmers and 116.20 deaths among nonfarmers. (Actual deaths numbered 1,138 farmers and 1,460 nonfarmers. Because Iowa has more nonfarmers than farmers, the actual number of deaths can be higher among nonfarmers yet their mortality rate can be lower.)

Multiple myeloma rate is 22.19 deaths among farmers and 11.97 among nonfarmers. (Actual deaths numbered 133 farmers and 172 nonfarmers.)

Stomach cancer rate is 56.28 deaths among farmers and 34.52 among nonfarmers. (Actual deaths numbered 338 farmers and 527 nonfarmers.)

Leukemia rate is 57.64 deaths among farmers and 34.61 among nonfarmers. (Actual deaths numbered 332 farmers and 545 nonfarmers.)

Lymphatic cancer rate is 33.41 deaths among farmers and 21.08 among nonfarmers. (Actual deaths numbered 208 farmers and 391 nonfarmers.)

Lip cancer rate is 3.46 among farmers and .94 (less than one) among nonfarmers. (Actual deaths numbered 20 farmers and 11 nonfarmers.)

Lung cancer rate is 230.12 among farmers and 283.86 among nonfarmers. (Actual deaths numbered 1,466 farmers and 4,828 nonfarmers.)

According to this study, cancer of the large intestine is also striking large numbers of Iowa's white males. There were 1,064 deaths among farmers and 1,952 deaths among nonfarmers during this period.

Only farmers under age 65 have a significantly higher death rate than nonfarmers from cancer of the large intestine. The adjusted mortality rate was 178.28 farmers' deaths and 128.44 nonfarmers' deaths per 100,000 population.

Though reasons for these occupational differences have yet to be proven, Burmeister and his colleagues do suspect such factors as type of farming, animal viruses, farm chemicals, equipment use, and dust from hay and ensilage.

"Studies in the southeastern states have associated multiple myeloma with poultry farming," says Burmeister. "In looking for a cause for a cancer, Iowa's current production patterns are not as important as the pattern 20 years ago since scientists usually assume a 20-year lag period between occupational exposure and development of the specified cancer.

"Iowa ranked first among states in chicken production in 1950 and second in 1960. In turkey production, it ranked third among states in both 1950 and 1960. Consequently, we'll be studying poultry production as a possibility here."

Higher leukemia rates have been found in counties where dairy farming is common, leading U of I researchers to suspect a relationship between leukemia and dairy cattle.

Kelley Donham, U of I associate professor of preventive medicine and environmental health, is studying this link and, in particular, the possible transmission of a virus, which causes a type of lymph cancer in cattle, from infected cows to man.

"Milk from infected cows is a method of transmission of the virus from cow to calf. We are studying the potential of this virus to be transmitted to man through raw milk," said Donham.

Researchers elsewhere have found increased stomach cancer among dairy farmers. The incidence of stomach cancer in Iowa is generally higher in the state's northern half, where most of the dairy farms are located, said Burmeister.

Other U of I researchers, Drs. Peter Isacson and Judy Bean, are currently studying the relationship between stomach cancer and water hardness. Isacson is head of the Department of Preventive Medicine and Environmental Health.

For prostatic cancer, no studies have yet identified a reason for occupational differences, said Burmeister. He speculates that the constant jarring of tractor-riding may contribute to the higher incidence among farmers.

The higher mortality rate for lip cancer is presumably due to excessive sun exposure, continued the statistician. However, it is not a common cause of death—31 persons died from it during 1971–1978.

Also related to sun exposure is skin cancer, which other researchers have also found to be more common among persons with outdoor occupations. Usually treated before it becomes severe, skin cancer has a low mortality rate.

Farmers under 65 years of age do have a significantly greater risks of skin cancer deaths than nonfarmers. For skin cancer, the death rate is 16.4 among farmers and 10.98 among nonfarmers for every 100,000 persons. Deaths numbered 105 farmers and 208 nonfarmers during this eight-year period.

"Cancer is basically considered an urban disease because of smoking habits and industrial exposure, yet we are finding that 'healthy' farm life has its cancer risks," said Burmeister.

Since reasons for these elevated cancer mortality rates have not yet been identified, Burmeister and his colleagues are currently studying the lifestyle and farming operations of the state's farm cancer victims and have submitted additional proposals to the National Cancer Institute to expand present studies.

THE UNIVERSITY OF IOWA HEALTH NEWS SERVICE--EARLY DETECTION CAN PREVENT SOME PROSTATE CANCER DEATHS

(By Kay Brief)

IOWA CITY, IOWA.—Many American men die needlessly from prostate cancer, which is the second-leading cause of cancer deaths among American men, says a University of Iowa urologist.

"By the time prostate cancer is usually detected, only about 18 percent of the patients have any chance for curative surgery," says Dr. David A. Culp, professor and head of the Department of Urology in the U of I College of Medicine.

"The vast majority of tumors are not detected until they reach the most advanced stage—the cancer has spread to the pelvis, bone or lymph nodes. According to our own preliminary studies, 57 percent of the persons who come to University Hospitals for prostate cancer treatment have reached this advanced stage by their first visit," Culp says.

Culp is currently studying the records of the 3,500 prostate cancer cases at University Hospitals since 1950. Approximately 2,500 cases have been analyzed so far.

Early detection is the key, he stresses.

"We recommend that all men over the age of 50 have two rectal exams a year by their physicians. If a physician finds a small nodule, it can usually be treated successfully through surgery, cryosurgery (chemically freezing and destroying the tumor) or radiation."

Prostate cancer is usually symptom-free until its advanced stages. An obstruction develops at the bladder neck within the urethra which may cause voiding problems.

Some symptoms are painful urination, changes in the voiding pattern (getting up to urinate, for example), or blood or pus in the urine. Some symptoms seem unrelated, such as pain in the bones.

Based on National Cancer Institute statistics, the American Cancer Society estimates that in 1980 a total of 22,000 U.S. men, including 350 Iowans, will die from prostate cancer and that 66,000 new cases among all U.S. men, including 1,200 Iowa cases, will be diagnosed.

STATEMENT OF JEFFERSON D. KEITH, EXECUTIVE VICE PRESIDENT, NATIONAL PEST CONTROL ASSOCIATION

Mr. Chairman and Members of the Committee:

My name is Jefferson Keith. I am the chief executive officer for the National Pest Control Association. NPCA is the national membership association of owner/operators of structural, general household, industrial and institutional pest control companies in the United States. Our membership includes the trade associations in this broad field, usually referred to as "structural" pest control, at state and local levels. Companies nationwide manufacturing and distributing pest control chemicals and equipment participate as Allied Members.

On behalf of NPCA and its members, I thank the Committee for this opportunity to present our experience in working with pesticides under the provisions of the current FIFRA[1] and our recommendations for amendments to the Act to improve its effectiveness in protecting the public health, our food supply and our building structures from pest infestations and disease vectors carried by these pests.

Our comments today will be limited to:

1. Concerns with the current FIFRA lack of clarity for the State level as the prime regulatory authority for pesticide registration and use.

2. To prevent State regulatory authorities from duplicating the registration costs to pesticide manufacturers and thus increasing the cost for these essential resources for pest control to the user community and thus to the public at large.

3. To request continuing support for the State programs of certification and training of commercial pest control operators.

Recommendations for correcting these problems have been introduced by Senator Hayakawa in Senate Bill 2621. Also, we wish to bring to your attention particular activities EPA has done well in cooperation with our Association and others in administering FIFRA over the past year.

At this point, let me tell you briefly about structural pest control. Members of the structural pest control industry are concerned with identifying and controlling pests that invade our homes, offices, factories and warehouses. This industry is the nation's defense against economic and aesthetic losses from all species of organisms that infest building structures or their contents. Our members also fight the battle to keep our food supplies free of contamination from pests once food leaves the field.

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[1] Federal Insecticide, Fungicide and Rodenticide Act (as Amended, 1978).

Structural pest control operators work to reduce the losses of the nations's food supplies from pest infestations during storage, transportation, processing and distribution up to the time it is consumed. We protect the public's health from animals and insects that may be poisonous, such as snakes and spiders, and pests, like rats and cockroaches, that serve as carriers of filth and disease as well as from organisms that are common nuisances such as ants, wasps, fleas and scorpions.

The structural pest control industry has used integrated pest management for many years. It has not and does not now depend exclusively on pesticides in its work. Pesticides are an important resource for eliminating and controlling certain pest infestations. The members of this industry depend primarily upon their knowledge of pest biology and behavior and their experience with a diversity of control methods appropriate for the site rather than dependence upon pesticides likely to be hazardous to them or their customers. We estimate that 95 percent of pesticides used in our industry are the same ones approved for use by the general public.

In the early 1970's NPCA supported the legislation which gave the EPA authority to regulate the use of pesticides. The Association actively supported EPA approved programs of certification of persons who apply, or supervise technicians in applying, pesticides classified by EPA and the States for "restricted use". It is and has been the policy of NPCA, and thus its membership, to use only those pesticides which are registered by the responsible authorities of State and Federal Governments and to use such materials in a manner described in the manufacturer's registered label and as recommended by professional authorities in our field.

For our purposes today in considering needed amendments in the reauthorization for the FIFRA for 1982-83 fiscal year, I will present three recommended amendments for your consideration. In our opinion, the amendments proposed by Senator Hayakawa in S.2621 bring about the needed changes we address in this testimony.

PROBLEMS AND CONCERNS:

1. Local county, township or city pesticide use regulations in addition to those at the State and Federal levels.

   During 1981 and 1982 political subdivisions within a number of States have attempted action, and in some instances adopted ordinances, to set their own rules and licensing provisions for what pesticides are to be allowed for use and the method for their application. Efforts of this type have been brought to our attention in the States of Massachusetts, New Jersey, NY, and Oregon within the past two years. In all instances that have come to our attention, the question of the legality of less than State level pesticide regulation has been questioned. In Massachusetts and NY the Attorney General submitted a ruling that local ordinances regulating pesticides were not legal. In other areas such definitive decisions have not been forthcoming or are pending a decision by the State legal authority. The promise of fragmentation of responsibility within a State for pesticide use policies endangers the public health and safety by increasing the difficulty for the pesticide user community to know what rules apply, at what time and to whom in the areas that he lives or serves as a commercial applicator.

In every request for local authority, the political township did not have the expertise to make risk versus benefit decisions on pesticides. They were reacting to fears or suspicions about chemicals without determing the facts on need from the State or elsewhere.

Control of pesticides is now provided by the U. S. Government and the fifty States and territories in a relatively uniform matter which is considered essential in the production, marketing and use of pesticides. Therefore, the U. S. Congress recognized and included in its deliberations, when FIFRA was amended by the 92nd Congress, that further regulation by subunits of State governments, including county and city governments, was not in the best national interest. Committee Reports S.R. 92-838 and H.R. 92-511 state clearly that the absence of language in FIFRA granting such authority at less than State levels of government displayed Congressional intent not to permit the regulation of pesticides by political subdivisions of States.

Without a clear provision in FIFRA to declare the intent of Congress on this matter in the statute itself, the decision on it has become subject to individual State level action that threatens to fragment responsibility for pesticides regulation and create confusion in the user community as to what are the rules for use of pesticides, to whom they apply and under what conditions. This could pose a threat to protection of both the environment and human health in the use of pesticides by the commercial applicator community as well as by the general public.

We recommend support of the amendments to Sections 24(a) and 26 in S.2621 that clarifies State authority by stating that a State shall not be deemed to include any of its political subdivisions or any agency thereof for the purposes of the authority for pesticide use regulations and their enforcement. This would not interfere with the State delegating responsibility for enforcement action to officials at less than the State level for carrying out State policies.

2. Costly duplication by States with requests for pesticide registration data supplied to EPA by manufacturers and formulators increasing costs to the public and the whole user community.

The NPCA depends upon the nation's pesticide manufacturers and formulators for essential resources with which to accomplish pest control at a reasonable cost so that our services can be made available to the general public at a reasonable cost. If the manufacturers', distributors' and users' costs are increased by unnecessary government administrative record keeping for registration or other purposes, the general public's cost for pest control services must also go up as will the taxes to pay for duplicative and unnecessary government report requirements.

There is a growing tendency by the States, led by the State of California, to adopt provisions requiring research data for the registration of pesticides that duplicate information already provided by registrants and formulators to EPA for pesticide registrations.

We feel that FIFRA needs to be amended to correct provisions that currently: A. Increase the nation's cost for pesticide chemicals and B. Reduce incentives for new product development.

In order to provide some relief to duplicative action by State government that is driving the costs for pesticide resources ever upward, we recommend support for the proposed amendments to Section 24(a) that are contained in S.2621. This amendment would not limit States in obtaining pesticide registrations for unique local needs under FIFRA Section 24(c) for experimental use purposes. It only asks that the State have a varifiable basis for requesting research data from pesticide registrants in addition to that that is supplied for the Federal registration. It does not interfere with the State's right to restrict or cancel pesticide uses within the State or to charge a fee for a license for pesticide registrations. This amendment, introduced by Senator Hayakawa, would reduce the States asking for registration data that duplicates or adds to that data which has already been supplied to EPA unless a valid reason for the requests exists.

3. Insufficient Federal funds for State programs for pesticide applicator certification training.

The budget authorizations for EPA by the House Agriculture Committee has provided significant reductions for most of the agency's operations. Included is a cut for pesticide applicator certification and training. Most of this training and testing activity is carried out by the States cooperatively with EPA through the States' Agriculture Extension Services. The EPA provides the funding for the pesticide applicator certification and training program under the direction of the Pesticides and Toxic Substances Enforcement Division.

Cuts in EPA appropriations to assist individual States to carryout their primacy functions may be necessary to reduce the Federal Government's total expenditures. We wish to point out, however, that Federal expenditures for pesticide applicator certification and training yields a much higher payoff in public protection per dollar spent than focusing money on penalizing violators since it is directed at prevention. The objectives are to assure that only properly qualified persons are certified to use pesticides and to provide continuing certification training to help applicators stay up-to-date on changing technology and on EPA decisions about newly discovered hazards and changing rules for use of pesticides. We feel the EPA Enforcement Division's funds spent on prevention of misuse rather than leveling penalties on people who may violate rules because they are not aware of new developments or changes by EPA or the State in pesticide label use directions is likely to be a better investment return than on each Federal dollar spent for collecting evidence for enforcement penalties. Both education and enforcement of the law are important; when properly balanced, they reinforce each other.

We urge the Committee to designate a minimum, rather than a maximum, of $4,000,000 for fiscal 1982-83 specifically for certification and training grants to the States. H.R.5203 places this amount as a maximum. These funds are for 50 percent matching by the States. Because of the need to reduce all Federal expenditures, if no increase is possible for this or any other activity, the Senate Committee may wish to consider setting this specific minimum for EPA to use for the State operated pesticide applicator certification and training programs.

Need for reciprocity.

Another related proposal we wish to make on this topic is also concerned with duplication of effort and time to meet the continuing certification requirements in neighboring States in a natural marketing area such as the North East. Each State may require the commercial applicator to meet the training requirements in their State without recognition of out-of-State training that is as good or better than that in the neighboring States in the North East. We urge the Committee in designating a minimum appropriation for commercial applicator certification and training programs by the States to make it available conditional upon agreement on reciprocity of qualifications for the certified applicators across State lines where there is interstate commerce in pest control. This helps to reduce the cost for pest control services by reducing the administrative costs of the commercial sector in meeting the duplicate requirements for certification and recertification every two to five years in each of the individual States.

NPCA COMPLIMENTS TO EPA ON PROGRESS:

I wish to take this opportunity to list for the Committee specific areas where EPA has done an outstanding job in working on issues that impact on our members.

During the past year we have found EPA cooperative with the structural pest control industry in the early development stages for:

- New interpretive regulations for Section 26 and 27 of FIFRA.
- Data collection upon which to base decisions on risks and benefits for selected pesticides to determine if a formal RPAR may be needed.

- Development of alternative approaches for disposal in a safe and practical manner unused supplies of the long-cancelled pesticide DDT that are still held by members of the structural control industry.

- Consulting with this industry and others representing urban pesticide applicators in related fields for methods of most effectively collecting data on pesticide usage.

- Consideration of industry proposals for enforcement policies to improve safety in pesticide application.

- More consistent use of recommendations provided to EPA by its independent Scientific Advisory Panel.

We are indeed encouraged by recent EPA staff action, as documented by the specific areas listed above, in working with this industry in developing regulatory actions that impact on us and the general public. Such a cooperative effort by government with industry to determine pesticide risks and benefits deserves recognition by our industry and wish to use this occasion to bring it to your attention.

CONCLUSION:

Mr. Chairman, in summary we support the proposed amendments to H.R. 5203 that are contained in S.2621 introduced by Senator Hayakawa to deal with some of the regulatory problems or concerns of our industry in the use of pesticides.

In addition, we are suggesting the Committee to specify a minimum, rather than a maximum, of $4,000,000 to be used in appropriations to EPA for support of pesticide applicator certification and training programs conducted by the States.

I will be glad to respond to any questions from the Committee on the topics we have present for your consideration and action today.

STATEMENT OF ROBERT J. FIELDS, DIRECTOR, REGULATORY AFFAIRS, FMC CORP.

Mr. Chairman, I am Robert J. Fields, Director of Regulatory Affairs, for FMC Corporation. FMC is a diversified manufacturer of machinery and chemicals with manufacturing facilities in 29 states and 14 foreign countries. My comments on the proposed amendments to FIFRA contained in S. 2620 are made from the vantage of a company which has had a long-standing commitment in the area of agricultural chemical research and development.

FMC is in strong support of the passage of S. 2620. Instead of commenting on each of the bill's various provisions, I would like to emphasize the need for one section of the bill which would amend Section 10 of FIFRA, the provision on the protection of trade secrets and other confidential business information.

Yesterday, this Committee heard testimony from Dr. Early, President of the National Agriculture Chemicals Association. In his testimony, Dr. Early mentioned that this bill represents several compromises worked out between the pesticide industry, representatives of public interest groups and labor organizations. One such compromise is that which appears in the proposed amendments to Section 10.

In June of 1981, when hearings similar to these were held before a subcommittee of the House Committee on Agriculture, industry's goal was to amend Section 10 in such a manner as to equitably and efficiently resolve problems due to the inadequate protection of commercially valuable research data. Our goal was then and still is to allow public access to health and safety data while ensuring that such data will not become available to our competition.

Competitive harm may arise if another company engaged in the research and/or production of agricultural chemicals gains access to data which we are required to submit to the U.S. Environmental Protection Agency. For example, a competitor could gain a detailed appreciation of the toxicity and environmental properties of a compound from these data. Such knowledge would give the competitor scientific leads of significant value. In addition, these data, if obtained by a competitor, may be used to obtain registrations for the compound in foreign countries. The value of these data, and the competitive harm which may be suffered from their unfettered release, has been well documented during extensive hearings before the House Committee on Agriculture.

S. 2620 would provide the agricultural chemicals industry with some additional protection for its data by establishing explicit criteria governing the disclosure of data submitted to the EPA. These added provisions were worked out during long and thoughtful negotiations between representatives of the industry, public interest organizations and organized labor.

Briefly stated, S. 2620 amends section 10 by providing significant controls on the disclosure, copying and transfer of research data in order to prevent the release of this information to pesticide producers and registrants who are in competition with the data owner. At the same time, this section continues to permit members of the public who have no competitive or commercial interest in the production or registration of pesticides to review health and safety information. The controls on copying and transfer of data are designed to safeguard the data from competitors, not to restrict access by non-competitors.

Under this provision, the general procedures for the release of data are revised to ensure that data submitters will be provided with a reasonable period of time, up to 60 days, in which to review data for the purpose of identifying portions that are trade secret, confidential, or contain innovative scientific methods. A data owner must be provided with 30 days notice prior to the initial public release of information claimed to be protected.

EPA is required to promulgate regulations under this section providing procedures for granting access to health and safety data, and prescribing conditions governing further copying or transfer of data, and for safeguarding of data. These regulations will give data owners an opportunity to confirm that persons who receive data from EPA are not affiliated with another pesticide producer or registrant, and will enable the data owner to keep a record of the number and location of copies of data that are in circulation.

This section prohibits EPA from disclosing information of a data submitter to any pesticide producer or registrant or to persons outside of the United States, or to foreign nationals who would remove the data from the United States.

Innovative scientific methods and technology are provided a further degree of protection in that they may generally be made available to scientists seeking to conduct a peer review of data but would not otherwise be given public distribution. This will enable data to be given full independent scientific scrutiny without releasing valuable innovative methods to persons with competitive interests.

Severe penalties are contained in the bill for persons who violate the disclosure provisions in furtherance of a commercial purpose involving the production, registration, distribution or sale of a pesticide. These penalties include the mandatory summary cancellation of all registrations issued to a violator and to anyone on whose behalf the violator was acting. These penalty provisions will help to preserve the competitive value of research data submitted to EPA.

It is, perhaps, almost as important to emphasize what S. 2620 does not do in its provisions amending Section 10 as compared to what it does accomplish. Charges have been made that the Section 10 amendments attack the balance of disclosure and protection of data. This is not so as will be evident to an impartial observer who takes the time to read the provision of Section 10. Statements have also been made that industry has sought to change the definition of trade secret. This also is incorrect—the definition of trade secret in S. 2620 remains unchanged from the 1978 Act.

Perhaps the greatest attack on the Section 10 amendment, and one which is, in my opinion, entirely overstated, deals with the protection to be afforded to innovative methods and technology. This provision relates to methods by which studies are conducted and is a very limited category of information. I must emphasize that this provision will not result in the withholding of health and safety data, nor will it affect peer review of the data. The House Committee on Agriculture Report on the FIFRA Amendments of 1982 summarized the effect of this amendment in its statement that "The Committee has structured the protections for innovative methods so that representatives of the public will have clear access to such data to perform the important function of independently reviewing the health and environmental effects of pesticides, thereby enabling them to evaluate regulatory decisions made by the Agency. Communications among such scientists and representatives regarding innovative methods is provided for, as well as procedures for decertifying such methods if necessary in the public interest."

In conclusion, the amendments to Section 10 allow the public to obtain complete copies of health and safety data but discourage competitive misuse of the data by enacting controls over its release and penalties for its illegal use.

STATEMENT OF MICHAEL C. FARRAR, VICE PRESIDENT, ENVIRONMENTAL AND HEALTH PROGRAM, NATIONAL FOREST PRODUCTS ASSOCIATION

Dear Mr. Chairman:

Your Committee will soon take up consideration of amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The bills introduced by you and Senator Hayakawa, S. 2620 and S. 2621, make some needed and helpful changes and reflect reasonable and long-debated compromises. The forest industry supports passage of these bills and offers the following comments.

The forest industry, through the National Forest Products Association (NFPA), has participated in the current round of deliberations on amending FIFRA since its beginning last summer in House Subcommittee. NFPA is a federation which includes 30 forest industry associations in addition to direct members. Through its membership, NFPA represents more than 2,500 companies throughout the United States and Canada engaged in timber growing as well as the manufacturing and distribution of forest products for housing, construction, furniture, shipping, energy, and a variety of other consumer and industrial products.

As a user of pesticides, the forest industry has been interested in FIFRA since it was first enacted. Our concerns include: maintaining the use of forest pesticides, assuring the scientific integrity of EPA decisions, and getting more pesticides available for use on forest nurseries.

As pesticide users, members of the forest industry are interested in gaining access to the health, safety, and environmental data required by EPA to register pesticides. At the same time, we recognize the proprietary nature of much of the data. The proposed amendment to Section 10 seems to have reached a reasonable and workable compromise.

Proposed Amendment to FIFRA Section 12

Your bill proposes to add a subparagraph Q to Section 12 of FIFRA protecting the employment status of an employee who exercises his rights under FIFRA. On its face, this is a difficult provision to oppose. But the forest industry vigorously opposed a similar provision in House debates when coupled with a penalty system administered by the Department of Labor. The forest industry maintains that: (1) no problem has been demonstrated to warrant the proposed amendment, (2) such a provision should not be transplanted from the Toxic Substances Control Act (TSCA) without extensive hearings on how it has been operating under that statute, (3) the proposed amendment has great potential for abuse, and (4) it is not necessary or wise to bring the Secretary of Labor into the enforcement of FIFRA for the first time.

"Employee Protection" provisions may well serve a valuable purpose in certain industries, but we have seen no evidence to support a finding that employees have been discriminated against for exercising their rights under FIFRA. We are certainly unaware of any such occurence in the forest industry. The House discussions did not touch on how the provision was operating under TSCA, let alone how a similar provision would operate under FIFRA. Absent such a discussion, it seems wrong to transplant a major provision of one environmental law into another.

The proposed amendment to Section 12 is not only unnecessary, but has great potential for abuse because employees could use the provision to insulate themselves from fully appropriate adverse employment actions. This potential for abuse is greatly increased because the proposed amendment uses the phrase "any other action to carry out the purposes" of FIFRA. A court may interpret that phrase broadly to include a large variety of actions giving someone greater latitude to allege a connection between that activity and an adverse employment action. The potential for abuse is somewhat reduced in S. 2620 from the House version because the Secretary of Labor will not be brought into FIFRA enforcement.

The forest industry's position here can be summarized by the phrase "if it isn't broken, don't fix it." This phrase is especially appropriate when the "fix" has great potential for abuse.

While the forest industry remains opposed to putting an employee protection provision in FIFRA at this time, we recognize the need for compromise in the legislative process. For this reason, the forest industry does not oppose S. 2620. However, should the Department of Labor be involved in enforcing the employee protection provision the forest industry would oppose the bill.

Proposed Amendment to FIFRA Section 25(d)

As stated earlier, one of the forest industry's prime interests in FIFRA is to assure the scientific integrity of EPA decisions. The reauthorization of the Scientific Advisory Panel in the proposed amendment to Section 25(d) is extremely important in helping assure that scientific integrity. Pesticide regulation has evolved into a highly emotional issue. EPA needs to make a strong effort to bring scientific judgment forward in an effort to make better decisions and counteract some of the emotionalism. We therefore strongly support the extension of the Scientific Advisory Panel.

Senator Hayakawa's Proposed Amendment to FIFRA Section 24(a)

In hearings before the House Subcommittee it was established that two basic problems exist in state registration of pesticides--long registration delays and unnecessary data generation requests. Such excessive state regulation will increasingly deprive consumers of the use of safe and effective pesticides. Senator Hayakawa's bill, S. 2621, sets reasonable standards for state regulation of pesticides to insure a proper balance between the role of the 50 states and EPA. Under the proposed amendment to Section 24(a) a state could still make any request for data if there is a "reasonable basis for making use of the data in connection with a state determination as to registration or approval of the pesticide."

Senator Hayakawa's bill would make two other important changes in FIFRA--set time limits for state consideration of a pesticide registration application, and restrict the authority to regulate pesticides to the state as a whole, specifically stating that political subdivisions of a state may not regulate pesticides. Delays of more than a year in acting on a state pesticide registration application, as is frequently the case in California, are costly to users who are denied the use of these chemical tools. The delays seem particularly senseless because they involve pesticides which already bear a federal label.

The bill would also specifically preempt subdivisions of states from regulating the sale or use of any federally registered pesticides. This provision would be particularly helpful to the forest industry which has been subjected to many county pesticide use restrictions. Political subdivisions of states are ill-equipped to regulate the sale or use of pesticides which requires weighing the risks and benefits of a pesticide use. Pesticide regulation at the local level leads to confusion as a federally-labeled use is allowed or not allowed depending on the county or town in which one wants to apply it. The current situation in which political subdivisions regulate the use of pesticides also creates a great opportunity for mischief as a small group can get a county to ban the use of safe and effective pesticides.

EPA and the states have the information and experience to regulate pesticides. Such decisions can currently be made at the local level without the procedures and experience which help make such decisions scientifically valid and fair on the state and federal levels. The forest industry supports Senator Hayakawa's proposed amendment to Section 24(a).

Private Right of Action

The forest industry is gratified to see that no amendment has been proposed to FIFRA Section 16. In House Committee deliberations some groups advocated an amendment to Section 16, giving individuals a private federal court right of action under FIFRA. Such an amendment is unnecessary because (1) adequate remedies already exist under state law, and (2) FIFRA enforcement procedures are already in place to stop pesticide misuse when it occurs. Also, adding a private right of action to FIFRA has great potential for abuse by those interested in stopping a pesticide spray project.

In virtually all states, citizens can already bring suit in state court for injunctive relief and damages. Almost all states have statutes defining pesticide use violations. In most states, citizens may bring suit to enforce their own state laws and therefore do not need a new federal right to sue.

In addition to enforcing state pesticide statutes, citizens also have the right to bring suit under state tort law for many actions which would constitute pesticide use violations. In a tort action the plaintiff would have to show negligence, but in virtually all states, use of a pesticide in violation of government laws and regulations would be negligence *per se* or, at least, strong evidence of negligence. Where an individual can show that he is entitled to equitable relief, virtually every state allows its citizens to obtain injunctions against such unlawful or negligent acts.

In addition to state pesticide and tort law, citizens can rely on established FIFRA enforcement procedures to stop pesticide misuse. Under FIFRA, a citizen may bring suspected pesticide use violations to the attention of state authorities for investigation and enforcement. The Administrator of EPA can act on the complaint if the state fails to act. States conduct hundreds of enforcement actions each year. There is no need to circumvent this workable and functioning system.

In short, there is no need for a new, broad and undefined right to bring private enforcement suits in federal courts. There are well-established remedies for pesticide use violations which already exist and have not been shown to be inadequate.

Even if later set aside, the temporary restraining orders and preliminary injunctions that would be sought under a private right of action in FIFRA would be of particular harm to the forest industry because of the crucial role timing plays in controlling forest pests. Many herbicide applications to control weeds that are taking over a young tree crop can safely be made only during a short interval, frequently less than a month, in the tree's annual dormant period. During that interval the applicator needs the proper weather conditions and can usually spray for only a few hours a day. Even a short delay occasioned by a frivolous suit likely would mean that much valuable acreage would not be treated.

To sum up, a private right of action should not be added to FIFRA because state remedies and federal enforcement procedures already exist and because it would have great potential for abuse. Thus, the forest industry would oppose any bill which included an amendment adding a private right of action to FIFRA.

Forest Nursery Pesticides

The forest industry has been facing another problem under FIFRA, getting more pesticides available for use on forest nurseries and seed orchards. This problem is currently being dealt with administratively at the direction of the House Agriculture Subcommittee on Department Operations, Research, and Foreign Agriculture. In hearings before that Subcommittee last summer, the forest industry, along with the nursery and florist industries, explained that because our crops are relatively quite small and valuable, effective pesticides, registered for other uses are not getting registered for these small nursery uses. A pesticide registrant has little incentive to add a non-food or non-feed nursery crop use to an existing pesticide label because of the small number of acres (small potential sales) and the high value of the crop (high potential liability).

EPA has been working on a policy, using the Administrator's authority under FIFRA Section 2(ee), to allow more flexible use of pesticides in non-food and non-feed nurseries and seed orchards. FIFRA makes it illegal "to use any pesticide in a manner inconsistent with its labeling." Section 2(ee) states that "any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act" is not to be considered the prohibited act of using "any registered pesticide in a manner inconsistent with its labeling."

EPA is considering a determination that, under certain conditions, use of food-crop pesticides on non-food and non-feed nursery crops would not be considered inconsistent with the pesticide label. Such a determination would be very helpful to the forest industry.

Thus far, EPA has been most responsive to our needs on this matter and we remain optimistic that EPA will publish a policy allowing more flexible use of food crop pesticides on our forest nurseries and seed orchards.

We hope that the Committee will give every consideration to these important issues in its deliberations on FIFRA.

TESTIMONY

BEFORE THE

SENATE AGRICULTURE COMMITTEE

ON

THE FEDERAL INSECTICIDE FUNGICIDE AND RODENTICIDE ACT (FIFRA)

JUNE 22, 1982

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Chemical companies and user groups support the House and Senate amendments reauthorizing FIFRA whereas labor, consumer, and environmental groups oppose the bill. The reasons are basic. Both House and Senate bills give companies who produce chemicals and those who use them legislative language that protects their interests.

Substantive legislation to protect the interests of environmental, consumer and labor groups is conspicuously sparse in H.R. 5203, S. 2620 and S. 2621.

In 1972 it was believed that premarket testing would bring about regulation of chemicals before use so that if problems were known prior to marketing, adverse effects could be averted through label precautions or restrictions on use. Restrictions were even seen as an alternative to outright cancellation.

By 1978 EPA was hopelessly backlogged in both classifying and evaluating studies submitted for old regulations. Conditional registration was requested in order to shorten time for registration. Trade secrets were defined to disclose to the public, health, safety and environmental data submitted to EPA in support of the old registrations. It was anticipated that the possibility of independent scrutiny would help to keep everyone more honest -- EPA and industry.

It is a decade after the hallmark 1972 legislation was passed. When reauthorization hearings began on the House side in 1981, we did not ask for new authorities, believing a simple reauthorization would allow EPA to resolve regulatory problems. EPA also requested only a simple reauthorization. Instead, proposed amendments cover 84 pages of the printed bill in the House, and 11 solid pages of the Congressional Record for the Senate version. We submit that a few changes could correct the gross inequity existing in the proposed amendments.

Trade secrets

The 1972 Pesticide (Federal Insecticide Fungicide and Rodenticide Act (FIFRA)) provided for release of information submitted in support of a registration to the public thirty days after EPA approval. The public did not get information because EPA had to get the company's permission to release the data, and industry claimed all information "confidential," and therefore unreleasable. In most cases, companies also claimed that since "trade secret" information was interspersed throughout their documents, it was impossible to separate out trade secret information from disclosable information. Thus, no data was released.

In 1978 Congress passed amendments to FIFRA defining trade secrets as

* manufacturing or quality control processes,
* details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide (formulation),
* identity or percentage quantity of any deliberately added inert ingredient of a pesticide,
* information on production, distribution, sale, or inventories.

Information which Congress said should be disclosed included:

* objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products,
* any information concerning the effects of such a pesticide on any organism or the behavior of such pesticide in the environment, including data on
    fish
    wildlife
    humans
    other mammals
    plants
    animals
    soil
    studies on persistence
    translocation
    fate in the environment
    metabolism

By defining trade secrets and releasable data, Congress sought to have health, safety and environmental data disclosed to the public.

Immediately after the 1978 amendments passed, nearly all chemical companies amended ongoing court suits, to enjoin EPA from releasing any information to the public. In June, 1981 three of the ten suits denied their claim of private property for their data, and the courts declared the data disclosable. The trade associations for the companies thereupon went to Congress to try to change the law.

After several hearings and business meetings in 1981, the House subcommittee introduced a bill February 4, 1982 which proposed to release health, safety and environmental data to the public through regional reading rooms. When no support could be found for changes proposed for Section 10, Chairman George Brown instructed EPA to produce a creative solution. That solution, written in large part by National Agricultural Chemicals Association lawyers, surfaced in mid-February as the amendment in the nature of a substitute to H.R. 5203, and became, with refinements, today's H.R. 5203, S. 2620 and S. 2621.

Innovative methodology

Contained in the substitute amendment for Section 10 was the first mention of innovative methodology:

> innovative utilization of new technology or unique combinations of new and/or known technologies employed in obtaining data for registration of a pesticide which, if disclosed, could cause a significant competitive disadvantage to the submitter of the data.

This concept was first brought up in the July 22, 1981 hearing of the subcommittee. Monsanto representative, Will Carpenter, told the subcommittee that its new mechanisms or methodology for analyzing Roundup, radiosynthesis, was not technically a trade secret within the definition of the 1978 language, because it is not "part of the manufacturing process." It belongs, Dr. Carpenter explained, "in the metabolism, the toxicology, and perhaps, even in some cases, the environmental arena." Its purpose is "discovering the fate of the molecule." The herbicide he was discussing, glyphosate, is patented in about 40 different countries, but Monsanto has not sought a patent on the radiosynthesis process. Dr. Carpenter went on "(the process) isn't something you could afford to put in the red book and say that truly is confidential and we show it to no one. If you go on the premise that you do need to make this publicly available for protection of public health and safety, then, this methodology that we are discussing, the scientists would need to look at it as well because one flows from the other." (Hearings at 642)

Despite several attempts to define "innovative methodology," or to say what it is not, it remains as vague as the July 22, 1981 characterization. In both House and Senate language innovative method or technology must be new, not otherwise available to the public and "used for the purpose of obtaining product chemistry, environmental chemistry, residue chemistry, or metabolism data."

This provision redefines what is disclosable under Section 10(d) by placing legally disclosable environmental data under wraps as "innovative methodology." Even worse, it appears to be a smoke screen by which to deny access to environmental data currently disclosable under Section 10(d).

Although an appeal process is provided to compell disclosure of the method, the burden of proof is on the independent reviewer. If one should succeed in persuading the Panel to allow disclosure of the methods to further an understanding of the fate of chemicals in the environment, and the Administrator accepts the decision, the company's appeal could still tie up release for several years. The methods would be denied to society for several years, even if everyone but the company believed the method should be disclosed.

The reason given for needing this protection for industry is a desire to retrieve a measure of financial reward for inventing a breakthrough process. Yet the patent process is available for industry, or licensing of exclusive use can also be obtained to retrieve developmental costs.

Audubon submits that the need for protection must be balanced against society's need for a better understanding of the environmental fate of chemicals and their breakdown products. Breakthroughs ought to be shared, evaluated and honored, not hidden under a cloak of secrecy for five years. We believe such information should be the intellectual property of scientists, researchers and the U.S. government, in attempting to find answers to questions on increasing and understanding productivity.

Audubon therefore opposes Section 10(a)(1)(B) which gives special protection to innovative methods and technology and urges this section be struck.

Standing to sue

It cannot be more strongly emphasized, there has been no release of health, safety and environmental data pursuant to the 1978 amendments. Some studies were conducted by EPA's Office of Research and Development throughout the past decade, to resolve problems identified as regulation and litigation proceeded. However, the budget for EPA R&D has been halved, diminishing the number of comprehensive and interdisciplinary studies likely to be undertaken in the next few years. In addition, RPAR documents that set forth good summaries of risks and benefits of reviewed compounds have, through the regulatory relief reform effort, been eliminated, will not be reviewed, or will be delayed indefinitely until adequate exposure data is obtained.

The most reliable information obtained in the past decade was almost entirely from court discovery in pesticide litigation with the Environmental Defense Fund representing Audubon. Now, however, because of a 1979 EPA reinterpretation of the 1972 FIFRA, standing to sue for public interest groups does not exist. Access to administrative review has been removed. A simple remedy could alter this imbalance by changing one word in FIFRA Section 6(b) to read (suggested language underlined):

> The proposed action shall become final and effective . . . unless within that time . . . a request for a hearing is made by any person adversely affected by the notice.

The suggested change involved striking "a," and substituting "any."

All this would do is explicitly to reiterate 1972 Congressional intent, embodied in the Senate report on FIFRA as follows:

> The Agriculture Committee bill . . . permits any citizen to initiate cancellation proceedings, obtain judicial review of every action and inaction he disagrees with, and intervene in every proceeding . . . (S. Rep. No. 92-838, Part II, 92nd Cong., 2d Sess. 39 (1972))

We urge the Senate to correct this inequity by changing this one word.

Private right of action

The inequity of the legislation before us is probably nowhere so stark as the provision for a private right of action to chemical companies for violation of disclosure of data in contrast to rejection of a private right of action for ordinary citizens.

Not only does industry have a private right of action against other companies or individuals, they may obtain treble damages, impose fines of $100,000 per document or study, and put parties in jail.

Audubon believes that fairness requires that if a private right of action is given to industry, it should be given to private citizens as well. We therefore urge that the following amendment be added to Section 16 of FIFRA.

> (e) Any person harmed by use of a pesticide in violation of this Act may bring suit in a United States district court having jurisdiction of the parties for equitable relief, damages and attorney's fees.

Legislation now embodied in H.R. 5203 and S. 2620 gives industry in addition to standing to sue, a private right of action against both other companies and private persons. Private parties or independent organizations are put at extreme disadvantage with this proposed legislation. We ask the Senate to remedy this imbalance.

Inert ingredients

The identity or percentage quantity of any inert ingredient deliberately added to a pesticide formulation is considered a bona fide trade secret by the 1978 amendments. Audubon hereby requests a change in the language of FIFRA Section 10(d) that would remove trade secret protection for the identity of inert ingredients. We request striking "identity of" from current Section 10(d)(1)(C) language as follows:

> . . . This paragraph does not authorize the disclosure of any information that -- . . . (c) discloses the percentage quantities of any deliberately added inert ingredient of a pesticide . . .

All pesticide formulations identify active ingredients and give a percent of inert ingredients on the label. The identity of inert ingredients is not necessarily on the label. One reason given for not listing inerts on the label is overburdening the label, already thought to be too detailed. Audubon submits that the distinction between inert and active ingredients is unclear, and is getting more indistinct. Not only are some inerts toxicologically active, EPA periodically exempts from a tolerance inerts that are occasionally active. In addition some active ingredients are being reclassified as inert ingredients. (March 25, 1982 EPA FR Notice) Most important, however, is the fact that in some formulations it is the "inert" ingredient that poses the hazard to man or the environment, and not the active ingredient. Therefore, the identity of inerts should be disclosed to the public.

In addition, the chemical characterization of inerts needs to be evaluated and regulated because of their presence in all pesticide formulations. Petroleum distillates alone are used in both active and inert ingredients in 70% of pesticide formulations. Since allergic reactions have been traced back to solvents in pesticides, rather than the active ingredient, their identity needs to be known for both treatment and contact avoidance.

Audubon submits the following proposed amendment to Section 3.

(i) Inert ingredients. -- The Administrator shall promulgate regulations by June 30, 1984 for identification and review of inerts contained in pesticide formulations, and requirements for tests for those inert ingredients designated as toxic, potentially toxic, or possessing synergistic capability.

Two recent studies demonstrated that inert ingredients may pose a toxic hazard to man.

> We are therefore led to the paradoxical conclusion that the carrier solvent in which an insecticide is formulated and applied might aid, under certain circumstances, in the survival of the target pest. The solvent carriers should not be regarded, as is often the case, as "inert" ingredients with little or no biological activity; their effects could provide a partial explanation for the variations in efficacy of different formulations of a given material. In view of our results, and in view of the widespread distribution of these solvents in many agricultural, industrial, and household products, it seems appropriate that the toxicology of some of these solvents to mammals and the potential toxicological interactions with other materials be more fully investigated. (Brattsten, L.B. and C.F. Wilkinson, Insecticide solvents: interference with insecticidal action, Science, 10 June 1977, 1211-13)

A second study found:

> The type of formulation in which a pesticide is dispersed can significantly affect the toxicity hazard . . . Little work has been done on insecticide carriers, and toxicological data are almost nonexistent. These carriers are usually considered nontoxic and therefore find wide use in industrial and domestic products. In addition they have received very little attention from environmental research groups or agencies. Consequently, we examined the toxicity of the particular solvent carriers in the insecticides. Our study shows that the emulsifiers and solvents are, in fact, active in vivo chemicals which influence viral lethality. (Crocker, J.F.S., and R.K Ozere, Lethal interaction of ubiquitous insecticide carriers with virus, Science, 25 June 1976, 1351-3)

These are our general concerns, concerns that could be met with simple changes in existing law or in S. 2620. We now turn to specific problems in the Senate language as printed in the Congressional Record, June 10, 1982.

Specific problems in the House and Senate Bills

FIFRA Section 3(c)(8) would be amended by H.R. 5203 as follows:

> "(D) A decision by the Administrator not to cancel or suspend the registration of a pesticide product or any use thereof or not to restrict the classification of a pesticide, following an interim administrative review, shall be subject to jucicial review under section 16(b) of this Act. Any final decision by the Administrator to such effect shall be deemed 'an order issued by the Administrator following a public hearing' for the purpose of section 16(b), and any person who has participated in an interim administrative review shall be deemed 'a party to the proceedings' for the purpose of that subsection." (Report No. 97-566 at 5)

The Senate counterpart is:

> "(D) A decision by the Administrator not to cancel or suspend the registration of a pesticide product or any use thereof or not to restrict the classification of a pesticide, following an interim administrative review, shall be subject to judicial review under section 16(a) of this Act, and any person who has participated in such interim administrative review shall have standing in any such judicial review proceeding."
>
> (Congressional Record, June 10, 1982 at S. 6676)

In effect, the Senate language does nothing. The House language only affects an agency decision not to cancel a use after an RPAR review. Audubon believes the only necessary change is the change of the word "a" to "any" in Section 6(b) of existing language, as explained above.

Science Advisory Panel

Section 8 of S. 2620 amends Section 25(d) of FIFRA, by extending the term of the Science Advisory Panel. The House proposed staggered terms for Panel members, representation from a range of disciplines, and an additional slate of nominees if necessary. Because the House version tries to ensure the continuity and apolitical quality of the Panel, Audubon supports the House version.

Farmworker safety

H.R. 5203 provides for safe working conditions (Sec. 25(f)), not included in the Senate bills.

For a decade, reentry standards have been regularly postponed for lack of data. What is needed is a comprehensive effort to initiate and establish safe reentry intervals, as well as studies to understand long-term and chronic effects due to pesticide exposure. Audubon therefore requests that a mandate be given to EPA to initiate immediately a program to increase medical knowledge of chronic and subtle effects of pesticides, as well as a system of reporting allergic reactions, chronic illness, or increased disease after pesticide exposure.

State authority

Section 24(a) would be amended by H.R. 5203 and S. 2621. Audubon opposes any restrictions on states rights to regulate pesticides. As states take over increased responsibility for regulation of pesticides, they need this authority unencumbered. The situation in California described by Senator Hayakawa in the June 10th *Congressional Record* has been remedied by Section 1119 of the 1981 Farm Bill (PL 97-98). That section, 7 U.S.C. 150dd, put into the Farm Bill by Senator Hayakawa, gives the Secretary of Agriculture authority to overrule a state for an emergency or crisis situation involving the introduction and dissemination of plant pests. Therefore, his reasons for amending 24(a) of FIFRA cannot support either the Senate or House language.

Conclusion

There is need to retrieve costs of research and development for pesticides. This makes it important for companies to obtain a market as quickly as possible, and to sell as much as possible within the patent life. With such a profit incentive, it is predictable to have the kind of legislation embodied in the bills before us today. The number of pesticides -- 1,500 active ingredients and 50,000 registrations -- is an indicator of the interest vested in registration, as is the 70% increase in pesticide production and application since 1970.

Also prevalent is the goal of screening chemicals for pesticide use -- target kill: lethality and percent of kill. This kind of search, however, brings the goal of target kill into direct conflict with the environment surrounding the target pest -- beneficial life, wildlife refuges, estuaries, people living near agricultural areas and so forth.

These directions need examination. Chemical companies should ask how to test and select for effective chemicals that will cause the least ecological disruption. If it means a chemical must be used only every two years to prolong effectiveness, legislation could be sought that might lengthen patent protection to allow longer years of safe use rather than a decade of disruption and conflict. We encourage a search for innovation of ways to protect the environment *and* the investment of chemical companies in such a search.

At a time when we are increasingly concerned with productivity, it would seem appropriate for Congress to require long term quality research on interactions of pesticides, pests and productivity. We need to look beyond short-term, and often cut-throat, profits. For the regulators, there is a need for long-term experiments and studies to measure residual or cumulative effects of pesticides in the environment. In short, Audubon urges an environment that encourages the kind of innovation that brings about better control of pests, more permanently, and more in harmony with life around target pests.

In the short term, and for the reasons stated, the National Audubon Society urges that Section 10(a)(1)(B) - innovative methodology, and Section 3(c)(8) - interim review appealed to the district court - be struck from proposed amendments. The amendments Audubon requests are:

(1) Add to Section 3(i) a requirement for regulations for inerts testing.

(2) Change "a" to "any" in Section 6(b).

(3) Strike "identity of" in Section 10(d)(1)(C).

(4) Add "involving production, registration, distribution or sale of a pesticide" to S. 2620 amendments to Section 10(h) and 10(i).

(5) Add private right of actions as Section 16(e).

(6) Mandate farmworker standards as Section 25(f).

S. 2621 should be rejected outright.

STATEMENT OF JAY FELDMAN, NATIONAL COORDINATOR, THE NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES ON S. 2620 AND OTHER PROPOSALS TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA).

June 22, 1982

Thank you for the opportunity to speak to you today about the serious pesticide problems faced by our nation and the need for a strong national pesticide law.

I represent the National Coalition Against the Misuse of Pesticides (NCAMP), which is a broad-based network of organizations and individuals in 50 states across the country. The coalition is composed of members with common concerns about pesticide hazards and safety, including family farmers, farmworkers, beekeepers, chemical workers and urban and rural residents. The coalition seeks protection for all who may be exposed to pesticides either through their employment, as consumers, or as neighbors of dump sites, sprayed fields, forests or right-of-ways. NCAMP promotes such alternatives to excessive pesticide use and misuse as Integrated Pest Management (IPM) in an effort to reduce damage to humans and the environment, ease economic burdens over the long run and improve general public and occupational health.

Introduction

Upon introducing S. 2620, the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982," Mr. Helms stated that since 1978 when FIFRA was amended significantly, "a number of problems have been encountered by the pesticide industry." As Mr. Helms explains it, the industry is concerned about the threat of "public access to health and safety data" on their products because of the disincentives that this creates to invest in pesticide product development.

While we nor members of the House Agriculture Committee have never seen any data which would substantiate the industry's claim, we have seen the data on the problems that the public and pesticide users have encountered since 1978 and before. The health and environmental problems faced by the public are not addressed by this bill, S. 2620.

We submit with all due respect, Mr. Chairman, that this approach to amending FIFRA as contained in S. 2620, is strikingly one-sided and throws the precarious balance of the Act dangerously off-center.

As you know, FIFRA is both a registration law and a public health and environmental law. While the chemical industry wants to see the law assure speedy marketing of their pesticide products and protections for investments in those products' development, the public and worker population of this country want to see this law protect them, their families and the environment from exposure to toxic pesticides which have both short and long-term health risk potential. In return for a registration number and exclusive-use periods that establish 10-year monopolies (15-year, if S. 2620 becomes law) on product sales, the manufacturer is required to produce evidence of a product's safety and effectiveness.

Note that the manufacturer is not required to show the "essentiality" of introducing yet another toxin into our homes, food, or workplace. Yes, Mr. Chairman, we are terribly concerned about a knee-jerk chemical response to pest problems when there often exist alternatives which are safer, less costly, and let me stress, more effective. The Congressional Office of Technology Assessment, in a 1980 special report, said an integrated pest management (IPM) approach, which utilizes a mixture of pesticides, natural predators and biological controls, can for major U.S. crops, "reduce pesticide (use) up to 75%, reduce preharvest pest-caused losses by 50% and reduce the total pest control costs by a significant amount."

The fact is, the public is faced with an increasing number of pesticide products on the market. From 1950 to 1970, overall pesticide production increased from 200,000 pounds to 1.4 billion pounds.[1] For the public to be concerned about the safe use of these products is natural. For Congress to ensure that these products are safe is imperative. For S. 2620 to simply consider industry concerns without addressing essential public health and environmental concerns is a tremendous disservice to our nation, now and to future generations.

Our overriding concern, then, relates to whether the public and workers of our country and those receiving products produced in the U.S. and sold outside our borders, are adequately protected from exposure to dangerous, potentially life-threatening, pesticides. The answer, Mr. Chairman, is a resounding no. Unfortunately, S. 2620 will only make matters worse.

I would like to share with you and the Committee how we go about answering this question in some detail. We start by looking at the state of pesticide safety and effectiveness in this country. To weigh the industry's and Mr. Helms' concerns in context, we look at the pesticide problems faced by the public and working people of our country. The remainder of my testimony will:

1. Outline the pesticide problem as we see it;
2. Explain how this problem will be exacerbated by S. 2620; and,
3. Propose a legislative solution that will preserve FIFRA and improve it in ways that will protect the public.

The Pesticide Program

Health: According to U.S. Environmental Protection Agency (EPA) estimates, a total of 45,000 people are treated for pesticide poisoning annually. The National

Study of Hospital Admitted Pesticide Poisonings estimates 3,000 cases of hospital-admitted pesticide poisonings with a 25% and 35% increase for farmers and farmworkers, respectively, over the last decade. A Medical University of South Carolina study concludes that for every hospital-admitted case a physician treats 15 office cases.[2] We believe these figures to be extremely low due to the fact that there does not exist in this country a mandatory pesticide reporting system. In fact, we believe the actual harm attributed to pesticides to be closer to the figures presented by the U.S. Department of Health, Education, and Welfare in 1970: 800 persons killed and 800,000 injured annually as a result of improper use of pesticides.[3]

The chemical industry recognizes the health problems associated with pesticide use and misuse. At their annual meeting in 1980, the president of the National Agricultural Chemicals (NACA) said, "In my judgement, involuntary exposure is becoming the central public health issue of the 1980's."

The January, 1981 report Chemical Hazards to Human Reproduction, issued by the Council on Environmental Quality, cites various studies of male and female workers exposed to pesticides. These studies report impotence, chromosome aberrations, infertility, miscarriage and other adverse effects on reproduction.

A University of Iowa study of farmers in that state found that six types of cancer pose greater risks to that population group than to city dwellers. According to the researchers, the cancer rate is an occupational hazard of farming and not related to smoking.[4]

Pesticides are turning up in wildlife, milk and in the nation's groundwater in case after case. Recently, North Carolina, Montana, Hawaii, Wisconsin, New York, California, as other states, have had to face questions of pesticide contamination of their food and water supply.

Tolerances and Food and Feed Products: A 1980 General Accounting Office (GAO) report, entitled Delays and Unresolved Issues Plague New Pesticide Protection Programs, indicates that there exists a severe deficiency in the tolerance setting program at EPA. The report reads,

> Our 1975 report to Congress stated that the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies. The situation has not improved. During our current review, an EPA official told us that the basis for many tolerances granted by the Food and Drug Administration is still obscure. According to the official, little, if any, documentation exists explaining how or why these toler-

> ances were granted. Additionally, the Assistant Administrator for Pesticides and Toxic Substances stated that not much difference exists between the present condition of EPA's test data files and those that existed at the time of our 1975 report.[5]

Despite the fact that the fungicide Captan was under EPA review for exceeding risk criteria, including potential mutagenic effects, the agency in September, 1981 proposed feeding corn seed coated with the chemical to hogs and beef cattle destined for the American dinner table.

Lack of Data: The same GAO report as cited above points to the fact that key health and safety data for most pesticides now in use have not been submitted to the EPA.

> [A]ccording to EPA officals, key tests required under current EPA regulations have not been performed for many of the 514 registration standards pestides. Included are long-term (up to 3 years) animal feeding studies which show whether a pesticide causes chronic effects, such as cancer or birth defects, in animals. An official told us that EPA needs the results of these tests to make even preliminary decisions concerning a pesticide's safety and whether it should be reregistered.[6]

Faulty Data: Furthermore, EPA, for years, has been accepting faulty health and environmental test data on pesticide products now on the market. One of the largest falsifiers of data, the Industrial Bio-Test Laboratories, Inc., provided EPA with more than 22,000 chemical safety tests. And while scientific opinion varies as to the reasons, more than 800,000 new cases of cancer are expected this year, and according to the Center for Disease Control nearly 3 out of every 100 children born in 1982 will have "serious birth defects."

Poor Enforcement of the Law: From an enforcement perspective, an October, 1981 GAO report, entitled Stronger Enforcement Needed Against the Misuse of Pesticides, suggests that the public and the environment are not protected from pesticide misuse because EPA and State enforcement programs exhibit the following characteristics:

> Many enforcement actions are questionable or inconsistent.
> Some cases are poorly investigated.
> State lead agencies often do not share EPA's enforcement philosophy.
> Most States lack the ability to impose civil penalties.[7]

Circumventing Registration Laws: The broad authority EPA exercises over pesticide use provides the administrator discretionary power to circumvent the very law intended to protect against adverse health effects. The GAO report cited above says that EPA and the States,

> are approving the use of pesticides for special local needs and emergency purposes which may be circumventing EPA's normal pesticide registration procedures.[8]

We believe that you can document a dramatic rise over the past year in the number of Section 18 emergency exemptions issued by EPA. Under Section 18, the administrator of EPA can exempt any Federal or State agency from any provision of FIFRA if she determines that an emergency condition exists. We urge the Committee to look into this matter.

Economic and Social Costs: While the magnitude of health problems due to pesticide exposure grows, some say in epidemic proportions, many researchers are calling attention to the diminishing returns associated with chemical pest management. Pesticide resistance has been reported in nearly 400 insect species.[9] And while the response may be to increase the dosages and potency of the pesticides, issue more emergency exemptions and special local need permits, insects appear to be fighting back with tremendous resiliency. Insecticide use has increased eleven-fold in the last thirty years, while crop loss due to insect resistance has doubled.

It has been estimated that it costs our nation $135 million in losses to the honey been industry due to poisoning and reduced pollination every year. All told, researchers have estimated that pesticides now cost our nation $839 million annually in losses attributed to environmental and social costs. Preliminary results include: $184 million in human pesticide poisonings; $12 million in livestock losses; $287 in reduced natural enemies and pesticide resistance; $135 million in honey bee poisonings and reduced pollination; $70 million in losses of crops and trees; $11 million in fish and wildlife losses, and, $140 million in miscellaneous losses such as government costs to respond to pesticide problems.[10]

A Small Farmer and Farmworker Speak: What does all this mean in human terms? Perhaps the best way to answer that is to listen to a family farmer and a farmworker, both integral parts of the food system in our nation and world and both directly touched by FIFRA.

> [Excerpts from testimony of C.J. Becnel, family farmer, Belle Chasse, Louisiana]
>
> Understand me well, I am a family farmer, as my ancestors were before me. We have nurtured, cared for, and cultivated our farms in the exact same general area since 1830 and we, farmers of this area, are

well aware of the benefits, in every respect of the proper use of pesticides. As said, the experiences to be related involved the gross misuse of pesticides.

A large neighboring farm by name of Citrus Lands of Louisiana, Inc., is comprised of some 30,000 acres. Starting in the early Spring of 1976, this farm put into effect a program to deforest a large portion of its property by aerial application of esters of various phenoxy herbicides, including, but not limited to, silvex and agent orange, the 50 percent each mixture of 2,4-D and 2,4,5-T.

That program was continued in 1977, again in 1978, and even until now. We had experienced severe problems of phenoxy drift, both in 1976 and 1977, and had called in our county agent who was unable to identify the causitive agent even though the symptoms from the gross misuse had manifested themselves on our crops and citrus stock and on ourselves personally and our families.

However, when such massive damage occurred in 1978, one of my sons and his wife, both of whom are graduate horticulturists, having degrees from Louisiana State University, investigated the problem and identified the damage as having been caused by a phenoxy herbicide.

We immediately called in the Louisiana Department of Agriculture pesticide enforcement people and the very mext day the chief of enforcement of pesticides, with his head inspector and others were on the scene. Even though he identified that neighbor as a cause and a continuing cause, the Louisiana Department of Agriculture has taken no action whatsoever against the misuser of pesticides.

From and since the early spring of 1978, the Louisiana Department of Agriculture, through its pesticide enforcement division, has manifested a very strong adversary position against us and our neighbors, having made highly questionable statements to us and publicly by appearing as witnesses on behalf of our legal opponent, and by making false statements and misrepresentation as to clearly indicate its lack of knowledge, interest, and concern for Louisiana's family farmers.

Throughout the years 1976, 1977, 1978, 1979, and 1980, use of the phenoxy herbicides and the involuntary exposure to their effects we have had many medical problems, of varying degrees, Some of our children have been hospitalized, some more than once.

We have, more or less, all had nausea, dizziness, rashes, viruses, stomach cramps, and other symptoms that a qualified medical expert has testified as phenoxy herbicide poisoning symptoms.

Our opponents quaintly refer to this serious problem as our "litany of complaints." My own wife has cancer which had its start some 6 to 8 months after our opponent acknowledged that the spraying had started; and my wife has, for more than 4 1/2 years, been subjected to several series of cobalt therapy, several surgical procedures, and is constantly treated by chemotherapy, and is considered a terminal cancer patient.

Our medical expert does not exclude the possibility of herbicide invasion as the cause or a contributing cause of this awful condition.

Now it is one thing for a family farmer to proceed to court for damages, but this is not why he plants crops. He plants crops to be able to harvest and sell his crops and not to have his crops destroyed by a neighbor who, through flagrant disregard of laws and regulations, misuses a pesticide and then attempts to avoid or at least delay restitution.

I realize that the burden of my song, thus far, has been to try to acquaint you with the fact that family farmers in our parish need help and protection that they are not receiving.

But where can they go? What can be done? We are well aware of the great forces that are being exerted by our chemical companies. Already our opponents have agreed that the economic life is more important than human life.[11]

[Excerpts from testimony of Josefina Castillo, farmworker, Mercedes, Texas]

My name is Josefina Castillo and I am 38 years old. Since I was 12 I have worked in the fields of Texas.

I have worked in many crops, including chile, cabbage, lettuce, beets, melons, and onions. I have three children and when they are not in school, they work with me.

What I want to tell you about are the problems we have with pesticides. It is often very hard to find work and now, because of the machines they use to harvest many crops and the expense of gasoline it is even harder.

But even when the work is good we often have to endure many hardships in the field. We go to work very early in the morning. Sometimes the pesticides will still be fresh and we will get the drops, like dew, on our skin.

Other times they will use powders which blow off or fall on your body while you are picking the crop. This makes your skin itch and bothers your eyes. Some days it will make you sick.

Other times, you will be working in the field and a plane will come and spray you. This has happened to me and to many people. It is as if pilots do not care that people are working in the fields. Most often it will happen when they are spraying nearby and the wind will carry the pesticide like light rain.

Several times during the last years I have gotten very sick. I got a bitter taste in my mouth and vomited. The pesticide irritated by body, and there was an intense pain in my eyes. My skin itched very much. Now it seems that I am more affected by the pesticides than before.

Many women, including myself, have had to work in the fields while we are pregnant. We have no choice, and many times a woman will lose a child or a child will be born with physical or mental problems.

I made a complaint about pesticides last year to the Texas Department of Agriculture. But they never told me if they did anything. They never told me anything at all.

But I must speak for all of the people, who, like me, must work out in the fields. And for all of them, I would ask you to do all that you can to see that workers are protected from the exposure to pesticides.[12]

S. 2620

Section 10: Restrictions on Public Health and Environmental Data Supporting Product Registration:

S. 2620, in addition to not addressing the sorry state of public protection from pesticides, weakens one of the central provisions of FIFRA, Section 10 data disclosure.

Under the existing Section 10 language of FIFRA, the public and scientific communities have a right to obtain pesticide health and environmental data, including methods of testing, test results and conclusions, on pesticide products registered with the U.S. Environmental Protection Agency. The existing law was painstakingly worked out in 1978 to protect as trade secrets manufacturing and quality control processes and the details of any methods for testing, detecting, or measuring [FIFRA, Section 10(d)(1)(A) and (B)].

The fact that Section 10(d)(1)(C) authorizes the identity of an inert ingredient only after the administrator of EPA determines it is necessary to protect against "unreasonable risk of injury to health or the environment" has been troubling to those working in public health. Because of this language, the independent review of these potentially harmful inert ingredients which may be biologically active, is impeded.

The point of Section 10 in its existing form is to allow full and open disclosure of health and environmental effects tests on active pesticide ingredients. S. 2620 will reverse Congressional intent as outlined in the present Section 10 provision.

Given the pesticide problem cited above -- the dangerous nature of the products we are dealing with and the faulty data that has been used to register products -- together with budgetary cutbacks, full and open disclosure becomes increasingly important.

The new Section 10(d)(2) to be created by S. 2620 would alter the existing data disclosure provision of FIFRA by creating a new quasi-trade secret category of health and environmental data defined as "innovative methods or technology (including innovative methods of using known technology)...employed in obtaining product chemistry, environmental chemistry, residue, and metabolism data...and innovative compositions of matter..."

S. 2620 would establish a prohibition on traditional, independent, scientific peer review on health and environmental data for a five year period. Scientific methods and data used to register pesticide products should be subjected to formal and full scientific review. This open peer review through the traditional method of publishing in scientific journals accomplishes two key objectives. It assures:

1. Informed public and worker decision-making on pesticide product use and exposure; and,

2. Improved EPA effectiveness by minimizing problems and biases that may be in health and environmental studies which have been submitted to EPA.

Informed public choice is a constitutional right. As cited in the Harvard Law Review, March, 1980, and in the courts,

> [I]t is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its policy power and in promotion of fair dealing, to require that the nature of the product be fairly set forth.[13]

S. 2620 very directly impairs the consumer's ability to make informed choices by hampering independent scientific and public review of chemical test data.

By way of example, I would like to illustrate the importance of ensuring that testing methods are in fact valid. Currently, staff within the EPA are recommending that toxaphene, a chlorinated-hydrocarbon and one of the most widely used insecticides in the U.S., be cancelled for all uses except as a cattle dip. Tests show the pesticide to produce thyroid carcinoma in rats, bio-accumulate and get in the food chain, as well as exhibit specific adverse effects on fish and other species in the environment. A former member of the Scientific Advisory Panel said that, "These areas of concern would lead me to control the exposure of the general population to toxaphene more stringently than other chlorinated hydrocarbon pesticides such as DDT, Endrin, Dieldrin, etc."[14]

One of the points of disagreement between the registrant of toxaphene, BFC Chemicals, Inc., and EPA staff relates to the question of a methodology used to detect levels of harm. In responding to BFC Chemicals' claim that the "Yazoo River Basin Model" is not validated by experimental verification, EPA maintains,

> The Yazoo River Basin Model utilized all available field data and is a published (emphasis mine) "state of the art" method for estimating environmental levels.[15]

Note that the agency is defending methodology on the basis of being "published 'state of the art'." We submit that there is no other way to know if a methodology, innovative or otherwise, is in fact valid. The kind of potential secrecy created by an amendment like this will only serve to create fear and anxiety in the minds of those using and exposed to pesticides.

Included in the "innovative methodology" definition and this special category of protections is the "innovative compositions of matter," or the identity of metabolites (breakdown products). Very often it is the transformation of a pesticide in the environment or in an organism that is the source of scientific, medical or environmental concern. Under S. 2620, scientists could not "identify" a metabolite considered innovative for the five year secrecy period.

It is our belief that the current trade secret definition contained in Section 10(d)(1) and 10(d)(1)(A), the exclusive use period and patent law offer sufficient protection for company investment in product development. To offer the additional protection the industry is seeking under the "innovative methodology" of S. 2620 would be to deny the public and their organizations participation in discussions about product safety.

Mr. Chairman, as you know, there has been much debate in the U.S. House of Representatives on this and other questions. Throughout that debate, the chemical industry lobby, the National Agricultural Chemicals Association (NACA), has produced no studies of the likelihood that disclosure of health and safety data would cause competitive harm, particularly overseas as has been claimed. To the contrary, studies of the drug industry indicate that little harm can be expected.[16] As Professor Thomas McGarity indicates, studies in anticipation of the 1978 amendments show that the pesticide industry in the U.S. is highly concentrated and profitable. McGarity maintains, "The burden should be upon the pesticide industry to demonstrate why the speculative possibility of lost profits in foreign markets warrants measures that would significantly impede public access to health and safety studies concerning chemicals to which humans and the environment are daily exposed."[17]

Amendments to Section 10(f) which restrict total access of information "to any foreign national" creates a tremendous double standard. Is the person using a U.S.-produced pesticide product in another country and seeking health and safety information any less deserving of that information than a resident of this country? No, of course not!

Health and environmental information on pesticide products, regardless of where they are produced or used, must be available to the user and to those potentially exposed. We urge that this reference to "foreign national" be dropped from S. 2620.

A Legislative Proposal to Preserve and Improve FIFRA

We are proposing eight changes to FIFRA which we feel will improve the law, better protect the public and meet the industry's concern about disclosure of health and environmental test data. Given the magnitude of the pesticide problem, NCAMP considers the following changes vital to our nation's health and environment.

Citizen Suit Provision: I will discuss in some detail our proposal to amend FIFRA by providing a citizen suit provision similar to that provided under the Clean Air Act and the Clean Water Act.

Our country is experiencing severe cutbacks in the agency that administers FIFRA. Cutbacks in budgets and cutbacks in terms of staff capability are anticipated in a wide variety of State agencies and particularly those charged with the enforcement of pesticide regulations. This does not bode well for agency enforcement of the provisions of FIFRA, either at the State or Federal level.

There simply are too few resources to do the job. The October, 1981 GAO report on pesticide enforcement suggests that even before massive budget cuts, the viability of the enforcement mechanism under the act was open to very serious question.

We are proposing an amendment to Section 16 of FIFRA which would provide victims of pesticide exposure access to the federal courts where they could seek protection against future harm. We believe that the attractiveness of the proposed change to Section 16 in this particular climate is that, unlike the current act, it allows victims of pesticide abuse and victims of pesticide misuse the opportunity to challenge FIFRA violations directly in court and does not force victims to seek help from Federal or State enforcement agencies.

Provisions of Section 16 allow the act to become self-enforcing and we think that is its real strength. Moreover, this amendment would afford the public the same access to the federal courts that is afforded the pesticide industry under Section 10(h), which would be created by S. 2620. Under this section, entitled Civil Action, the chemical industry is provided a private right of action for treble damages against violators of the act. It is only fair that the public is assured similar access to the judicial system.

In addition, NCAMP proposes that FIFRA be amended in the following ways:

1. Increase fines and data submitter penalties for those obtaining and/or using health and safety data in furtherance of a commercial purpose involving the production, registration, distribution or sale of a pesticide. [Amend Section 14.]

2. Provide for the disclosure of the identity of the so-called "inert" ingredients many of which are extremely dangerous to humans and the environment. [Amend Section 10 by deleting Section 10(d)(1)(B) and (C).]

3. Redefine unreasonable adverse effects to protect "workers", the "public", and "environmental costs and benefits of the use of any pesticide and the availability of alternative control methods." Unreasonable adverse effects also should take into account any threat to the reproductive health of workers and the public. [Amend Section 2(b).]

4. Grant standing to any person whose interests are adversely affected by a proposed EPA cancellation action. [Amend Section 6(b)(2).]

5. Protect workers alleging violation of this act from employer retalliation. [Amend Section 12(a)(2) and Section 14.]

6. Allow states flexibility to impose or continue in effect any requirements for labelling or packaging in addition to those required by FIFRA. [Amend Section 24(b).]

7. Ensure the issuance of regulations providing for: a. safe working conditions for field workers, persons storing, handling or applying pesticides, and others in the vicinity of pesticide-treated areas; b. documentation of pesticide applications by applicators; and, c. requirements for storing, warehousing and disposal of pesticides and pesticide containers.

Comments on Industry Proposals to Limit States' Ability to Regulate S. 2621

Mr. Chairman, you have heard of proposals to alter existing States' rights provision of FIFRA to, in effect, tie the hands of the States in the area of pesticide control. We urge you to reject this attack on the States' ability to protect its residents proposed by the Chemical Speciality Manufacturers Association (CSMA) and introduced by Mr. Hayakawa in the form of S. 2621.

States will typically use additional data not already collected by EPA to design a specific state pesticide regulation which is more protective than the federal standard. According to the GAO, key health and safety data for most pesticides now in use have never been submitted to EPA. This data gap exists because requirements for cancer, birth defects and genetic mutation data were imposed after the federal government had already registered most pesticides now in use.

The current FIFRA language establishes national uniformity through minimum federal standards across the country, but specifically allows States the flexibility to request additional data and exceed the federal standard. Without this data, States will be unable to regulate pesticides and forced to use the federal standard.

CSMA proposals to amend Section 24 of FIFRA shift the burden to the States to prove, through possibly long and costly court battles prior to the receipt of data, that they have a "special local concern" about a particular pesticide's effect. While not defined in any of CSMA's proposals, the implication is that the concern is one relatively unique in the State. The State, after enduring this process, is confronted with an arbitrary distinction between agricultural ("utilized in the production of a commercial food, feed or fiber, crop") and non-agricultural pesticides, which sets forth a State's ability to regulate.

With the CSMA proposal enacted, State authority would be most vulnerable to restriction for home, garden, forest, right-of-way and other non-agricultural uses of pesticides. These pesticide uses are however, responsible for most recorded poisonings, especially of children.

Regardless of company delays in submitting data on agricultural and non-agricultural pesticides, States would, under the CSMA proposal, be forced to "conditionally" put a product on the market within 60 days of an application.

The CSMA proposal creates a bureaucratic mess, to say the least, and will impede future and current State pesticide regulation. State authority to regulate the sale and use of pesticides is within the traditional police power of the States under the U.S. Constitution.

Thank you for the opportunity to present our position on S. 2620, S.2621, and the need for an effective federal pesticide control law. We urge this committee to consider seriously the health and environmental concerns as related to pesticide use and misuse, preserve the existing data disclosure and States' rights provisions in FIFRA and adopt our proposed changes which will better protect the people and land of our nation.

RESOURCES

[1] Samuel Epstein, The Politics of Cancer, New York: Anchor Press, 1979, p. 248 (compiled from statistics of the U.S. Department of Agriculture, 1979).

[2] U.S. Environmental Protection Agency, National Study of Hospital Admitted Pesticide Poisonings, 1976.

[3] S. Rep. No. 91-1282, 91st Congress, 2nd Session; reprinted in U.S. Code Cong. & Adm. News, (1970), pp. 5179-5180.

[4] Leon Burmeister, "Cancer Mortality in Iowa Farmers, 1971-78," JNCI, Vol. 66, No. 3, March, 1981, pp. 461-464.

[5] General Accounting Office, Delays and Unresolved Issues Plague New Pesticide Protection Programs, CED-80-32, February 15, 1980, p. 19.

[6] Ibid., p. 15.

[7] General Accounting Office, Stronger Enforcement Needed Against the Misuse of Pesticides, CED-82-5, October 15, 1981, p.ii.

[8] Ibid., p. i.

[9] Dale Bottrell, Integrated Pest Management, Council on Environmental Quality, December, 1979, p.9.

[10] David Pimentel, et. al., "Environmental and Social Costs of Pesticides: A Preliminary Assessment," Copenhagen: OIKOS, 34: 126-140(1980), p. 135.

[11] C.J. Becnel, Hearings on FIFRA -- Pt. 1, Before the Subcommittee on Department Operations, Research and Foreign Agriculture, 97th Cong., 2nd Sess., pp. 222-228.

[12] Josefina Castillo, Hearings on FIFRA -- Pt. 1, Before the Subcommittee on Department Operations, Research and Foreign Agriculture, 97th Cong., 2nd Sess., pp. 216-218.

[13] Thomas O. McGarity and Sidney A. Shapiro, "The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies," Harvard Law Review, March 1980, Vol. 93, No. 5, p. 867.

[14] Dr. Doull cited in U.S. Environmental Protection Agency, Special Pesticide Review Division, Internal Memorandum, Feb. 22, 1982, p. 3.

[15] U.S. EPA, Report: Agency Counter Proposal to BFC Chemicals' Proposal on Toxaphene, unpublished.

[16] Food and Drug Administration, Supplemental Analysis of Impact of the Provision in S. 2755 Regarding Disclosure of Safety and Effectiveness Data on Foreign Markets of Multinational Firms (undated); Hearings on Drug Regulation Reform Act -- Pt. 2, Before the Subcommittee on Health and Foreign Commerce, 95th Cong., 2nd Sess: 2162, Testimony of Dr. Roger Noll.

[17] Thomas O. McGarity, Hearing on FIFRA -- Pt. 1, Before the U.S. House of Representatives Subcommittee on Department Operations, Research and Foreign Agriculture, 97th Cong., 2nd Sess., p. 324.

NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES,
Washington, D.C., June 30, 1982.

Hon. S. I. HAYAKAWA,
U.S. Senate, Committee on Agriculture, Nutrition and Forestry, Russell Senate Office Building, Washington, D.C.

DEAR SENATOR HAYAKAWA: Enclosed please find material I referred to during my FIFRA testimony which I understand will be placed in the hearing record along with my statement.

We appreciate the opportunity to alert you to the serious problems associated with S. 2620 and S. 2621. We look forward to working with you in an effort to find remedies to these problems and construct an improved national pesticide law which adequately protects the public.

Sincerely,

JAY FELDMAN,
National Coordinator.

Enclosures: Insert information, Scientists' letters.

HARVARD UNIVERSITY,
Cambridge, Mass., April 22, 1982.

Representative GEORGE E. BROWN, Jr.

DEAR GEORGE: I have recently become aware of another matter, involving the proposed changes in the pesticide law (FIFRA). There is a new provision in the draft law that would allow "innovative methods or technology" to be kept secret from inspection and examination by the scientific community, for a period of five years after registration of the product or technique. Since these new methods and techniques might involve substantial risk to the public, which could be rapidly discovered if the scientific community had free access to the information, I think that this is a dangerous provision. There is, I believe, nothing at all like it in the present law. I can see why the chemical manufacturers would like such a provision in the law, but I think it is not in the public interest. I think that this provision in H.R. 5203 should be struck out.

I am also opposed to the proposed changes in Section 24 of FIFRA which would restrict the ability of states to gather data in order to impose their own regulations regarding pesticides. I understand that you are opposed to these provisions, and I hope that you will strongly resist their inclusion in the revised FIFRA.

Yours sincerely,

JOHN T. EDSALL,
Professor Emeritus of Biochemistry.

CORNELL UNIVERSITY,
PROGRAM ON SCIENCE, TECHNOLOGY & SOCIETY,
Ithaca, N.Y., April 23, 1982.

Hon. GEORGE E. BROWN, Jr.,
Chairman, Subcommittee on Department Operations, Research and Foreign Agriculture, House Committee on Agriculture, Rayburn House Office Building, Washington, D.C.

DEAR CONGRESSMAN BROWN: We are writing to express our concern about recent proposals to amend the Federal Insecticide and Rodenticide Act (FIFRA). We are particularly concerned about the proposed restrictions on the availability of data concerning "innovative methods." This restriction would inevitably preclude the public discussion that is a fundamental part of the democratic process and the public's right to know. It would also preclude the scientific debate necessary for verifying questions of health and safety.

In addition the amendments would place an additional burden on EPA on the assumption that this agency will and can assume responsibility for the evaluation of innovative methods. It is evident that EPA at present places low priority on the pesticide program. Moveover, the agency traditionally has relied on external scientific review of scientific issues, a possibility that would be precluded by the new amendments.

Finally, the amendments seem to be yet another means of information control, a topic that you have spoken on eloquently in other contexts with reference to proposed changes in the FOIA and export controls.

We hope that you and your colleagues will oppose any changes limiting open scientific discussion of product test methods.

Sincerely yours,

DOROTHY NELKIN, *Professor.*
MICHAEL BROWN, *Research Assoc.*

[Mailgram]

GAINESVILLE, FLA., *May 4, 1982.*

The following telegram was sent to Representative Don Fuqua, House of Representives, Washington, D.C.:

We are writing to express our concern about proposals as contained in H.R. 5203 to amend FIFRA, because of your role as chairman of the House Science and Technology Committee we want to discuss with you proposed restrictions on the availability of data concerning innovative methods and technology.

We have questions about the potential danger of precluding scientific debate necessary for verifying questions of health, safety and environmental effects.

We are concerned that this would preclude independent peer review and discussion in the scientific literature which are necessary to validate the usefullness and reliability of innovative testing methods and technology.

In addition, three is provision in these amendments for Federal pre-emption of local regulation which would result in the superseding of Florida law.

Above all, we are particularly concerned about the potential burden on EPA and whether the agency can assume the responsibility for evaluation of innovative methods. The agency has traditionally relied on external scientific review of scientific issues.

We therefore urge you to take up these matters in hearings in your own committee before H.R. 5203 goes to the House floor. Kindly inform us of action taken by your office.

With thanks for your past aid to our scientific community at the University of Florida at Gainesville.

DR. DANIEL B. WARD.
DR. CHARLES REID.
DR. DAVID ANTHONY.
DR. REECE SAILER.
DR. BARNEY CAPEHART.
DR. REBECCA KEMAL.

UNIVERSITY OF WISCONSIN,
Madison, Wis.

Congressman DAVID OBEY,
Rayburn House Office Building,
Washington, D.C.

These comments are addressed to the status of the national pesticide law currently before the U.S. House of Representatives. H.R. 5203, amending the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) would weaken the abilities of research workers, policy makers and concerned citizens to prevent health and environmental damage from misuse of pesticides.

The bill (H.R. 5203) would place limits on the flow of information and make it more difficult for state governments, citizens and scientists to gain access to pesticide environmental and health effects study data. Specifically, section 11 shifting the burden of proof to states and restricting states' abilities to design pesticide standards and section 5 limiting data review to verify manufacturer safety claims are unacceptable.

In fact, the laws regulating most pesticide usage are in need of more vigorous enforcement and new policy and research work is crucial to prevent future problems. A citizen suit provision similar to that in other environmental legislation, could strengthen the Federal Insecticide, Fungicide and Rodenticide Act. An accelerated program of research work and occupational monitoring of pesticide workers could help prevent detriments to worker and consumer health and well being.

It is important to note that a large portion of the existent testing information on pesticides is questionable and comes from studies done by an Illinois firm. Independent scientific review has established that much of this research work was invalid and fraudulent. Careful review of pesticide health and safety research must continue to help prevent these types of abuses in the future. In addition, scientific research funding must be increased to test those pesticides currently in use with inadequate safety data. Ideally, this work would be performed by independent scientists without an economic interest in the research results. We strongly urge you to address these concerns and consider joining with your colleagues in letters supporting action to protect and improve pesticide law.

D. J. D'ALESSIO, M.D.
S. L. SAUTER, Ph.D.
M. S. KANAREK, Ph.D.
L. J. CHAPMAN, M.S.
K. R. ROHRER.

THE INVESTIGATION AND CLASSIFICATION OF INERT INGREDIENTS IN PESTICIDE FORMULATIONS: FINAL REPORT—SEPTEMBER 30, 1977—EPA CONTRACT 68-01-3431

(Submitted by Potomac Research, Inc., McLean, Va.)

TOXICOLOGICAL CLASSIFICATION

As data was collected on individual compounds, the inerts were toxicologically evaluated. Following a professional review of available literature, the inerts were categorized as:

Class 1.—This category of inerts contains those found to have chemical, toxicological or environmental characteristics that require immediate attention.

Class 2.—Available data indicate probable cause for alarm because chemcial structure is similar to a known toxicant, or a metabolic environmental pathway may result in breakdown to known toxicant, or irreversible chonic effects are known, e.g., neurotoxicity, irreversible eye damage, skin sensitization, etc. Massive fish kills or other environmental effects also triggers this category.

Class 3.—Hazard data inadequate for total review where it is apparent that the use of the inert would indicate certain test requirements.

Class 4.—No hazard data found or compete testing published i.e., ideal situations.

Class 5.—Nature of inert does not allow chemical definitions, i.e., manure, corn, rotten eggs, etc.: however, it is reasonable to assume no hazard exists.

Class 6.—Miscellaneous Class—errors in number or name; the name could not be properly identified, number incorrect, incorrect classification, etc.

Listed in Table 3 are those compounds which were assigned a Class 1 or 2 hazard classification.

TABLE 3. CLASS 1 AND 2 COMPOUNDS

EPA accession No.	Compound name	Hazard class
419	Phenarsazine oxide	1
623	Dimethylamine	1
692	Hydroxylamine Sulfate	1
695	Lead	1
734	2-Imidazolidinethione	1
766	Dioxane	1
781	Saccharin	1
914	2-Ethylhexanoic acid, nickel salt of	1
83	Diethanolamine oleate	2
272	7-Hydroxy-4-methylcoumarin	2

TABLE 3. CLASS 1 AND 2 COMPOUNDS—Continued

EPA accession No.	Compound name	Hazard class
298	1,3-Dibutyl-2-thiourea	2
308	alpha, beta-Exopy-beta-methylhydrocinnamic acid, ethyl ester of	2
316	Dichloroanilime	2
332	Tris (2-butoxyethyl) phosphate	2
343	1-Methyl-2-pyrrolidene	2
433	Citric acid, tris(trietylamine) salt of	2
435	Citric acid, tris(dimethylamine) salt of	2
455	Ethylenediaminetetraacetic acid, tetrakis (triethylamine) salt of	2
461	Ethylenediaminetetraacetic acid, tetrakis (diethanolamine) salt of	2
571	Triethylamine phosphate	2
595	7-(Diethylamino)-4-methylcoumarin	2
706	Diethylenetriamine	2
724	1-Amino-2-propanol nitrite	2
736	1,3-Diethyl-2-thiourea	2
751	Lead Chromate	2
752	N,N'-Dinitrosopentamethylene tetramine	2
763	Dicyanodiamide	2
777	Propylamine nitrite	2
795	Nitromethane	2
843	Nitrilotriacetic acid, tris (triethylamine) salt of	2
860	Aniline	2
882	Triethyl phosphate	2
895	Hexane	2
	Nonylphenol, barium salt of	2
	Toluic acid, cadimun salt of	2
	N-Ethyltoluenesulfonamide	2
	1,2-Eposybutane	2
981	Alpha, alpha-Dimethlbenzyl hydroperoxide	2
983	Atropine	2
1001	Maleic anhydride	2
1007	Dimethylether	2
1009	2,4,6-Trinitrophenol, sodium salt of	2
1034	2,2'-(Ethylamino) diethanol	2
1039	Diisopropanolamine	2
1069	Acetonitrile	2
1070	1,2,3-Benzotriazole	2
1085	Triethylamine	2
1093	2-Nitropropane	2
1116	Triethylamine Sulfate	2
1132	3,4-Epoxycyclohexanecarboxylic acid, (3,4-epoxycyclohexyl) methyl ester of	2
1193	tert-Butyl peroxide	2
1210	Dibutyldithiocarbamic acid, zinc salt of	2

STATEMENT OF RALPH LIGHTSTONE, ATTORNEY ON BEHALF OF MIGRANT LEGAL ACTION PROGRAM, CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION AND FARMWORKER JUSTICE FUND, INC.

Mr. Chairman and members, thank you for the opportunity to testify today on proposed amendments to the federal pesticide law, FIFRA (The Federal Insecticide, Fungicide, and Rodenticide Act). S. 2620 and S. 2621, which are currently before this committee, as well as H.R. 5203, which is pending in the House, propose major policy changes in the nation's pesticide laws.

The current law reflects past Congresional policy:

1) to improve federal pesticide regulation while preserving state authority to supplement federal action;

2) to assure that all interested persons are able to participate fully in the federal regulatory process; and

3) to release crucial industry-generated safety and efficacy studies to interested scientists and the public.

Each of the bills now before Congress contain provisions which significantly erode or neglect to address one or more of these concerns. These bills abandon past compromises and adopt the pesticide industry agenda to weaken federal and state pesticide laws at a time when growers, consumers and workers need assurance of improved controls to avoid the errors of the past.

State Authority

Section 24 of the current law authorizes the states to regulate the sale and use of pesticides within their borders with two basic limitations:

1) states cannot be less restrictive than the federal government (e.g. cannot approve a federally banned pesticide); and

2) states cannot change labeling or packaging, which are determined federally.

These provisions establish a national uniform labeling and packaging system, assure minimum national safety standards, and preserve the historic authority of states.

S. 2620 leaves the current provisions of section 24 unchanged, which we believe is the best course of action. The 1972 Congressional compromise that produced section 24 has worked well. The pesticide industry has expanded its national market during these years, and the states have been prudent in exercising their authority.

S. 2621 on the other hand, abandons the balance in the current law, and seeks to curtail vital state authority. If enacted, S. 2621 would replace the simple and concise language of FIFRA section 24 (a) with an expensive and complex bureaucratic scheme. It divides state-desired information into three categories, then provides for the federal EPA and the courts to review (and veto) state data requests. Even the state categorization of data requests is subject to protracted federal litigation.

One of the three data categories created by S. 2621 appears at section 24 (a) (2) (B). This provision would only allow a state to request information from a pesticide manufacturer about the safety or efficacy of its product with respect to a "special local concern" in that state after the state produced "signifiant factual evidence" that the pesticide was causing a problem there. This is a 'spray first, ask questions later approach' and it should be rejected. In the past, the states have followed this approach, even though FIFRA authorizes them to ask first. The results have demonstrated that more local data, not less, should be requested.

In the mid-1970's the EPA approved Torak, an organophosphate insecticide, for use in California grapes. Two problems followed. First, there were massive and severe poisonings of California grape harvest workers, including one case where 118 workers were poisoned. Second, Torak proved ineffective to control target pests on the grapes. The EPA and the state had failed to require sufficient residue degradation data, and efficacy data, on this product to protect workers and growers. California learned its lesson, and now requires such data for pesticide registrations there. S. 2621 however would provide serious obstacles to the state's ability to obtain such data prior to the type of disaster just described.

A second case involves a data requirement which is not a "special local concern" within the meaning of S. 2621. A rat poison, Vacor, was approved by the EPA and accepted by California in the 1970's. Due to inadequate packaging, and a similar appearance to peanut butter, it was ingested by children, and resulted in irreversible damage to insulin-producing cells of the pancreas. State officials then discovered that the registrant had failed to disclose more than 160 deaths from this product that had occured in Korea. Vacor was removed from the market. California now requires "mode-of-action" data on rodenticides, so that an accurate measure of potential harm is understood before such products are sold for home use. That requirement, will be subject to industry-initiated appeal and litigation, as well as EPA veto, under the provisions of category (C) data under S. 2621. S.2621 bars the states from obtaining judicial review of the administrator's veto. S. 2621, then, vests unreviewable authority in the Administrator of EPA to restrict state inquiries about home use pesticides such as Vacor, or agricultural pesticides (as to issues that are not "local").

Section 24 (a) (3) (C) under S. 2621 penalizes inquisitive states by blocking their ability to regulate the sale and use of a pesticide following the veto of a data request. It would not limit the state's authority to act, as long as the state doesn't seek more information from the applicant about the pesticide. Once it asks, the state's very power to regulate may be lost.

H. R. 5203 is similar to S. 2621 in that it rewrites the language of FIFRA section 24 to create three data categories and it also provides for a complex system of federal review of state data requests. Like S. 2621, it punishes inquisitive states. The primary difference is that H.R. 5203 limits the ability of EPA to veto state data requests in the area of agricultural pesticides. Therefore, the most interference with state action is contemplated for home use pesticides. Most poisoning occur in and around the home rather than in agriculture. The California poison control centers handle 14,000 home pesticide poisoning cases annually. The example of Vacor illustrates the necessity for preserving state authority for both home and agricultural pesticides.

S. 2621 also contains provisions which eliminate local, as opposed to state, control over the sale and use of pesticides. The provisions are apparently directed at several west coast counties that have either adopted ordinances, or had local elections on the issue of aerial application of phenoxy herbicides in their communities. It is a major policy shift for Congress to block such local activities. In addition, the scope of the language would reach far beyond the phenoxy herbicide controversy. Various local jurisdictions have adopted ordinances governing the use of pesticides in parks and public areas. Others have experienced fatal accidents with home fumigation, and have adopted special local safeguards to guard fumigated houses during the dangerous period. Still others, such as Monterey County, have adopted special field posting ordinances. The Monterey action was based on a consensus among growers and farmworkers that posting of sprayed field would prevent accidental poisonings. All of these local government actions are jeopardized by the language of S. 2621.

S. 2621, and H. R. 5203 both propose to significantly expand federal power, and reduce state and local power in the regulation of pesticides. We doubt that the federal government has either the ability, or the resources to assume this awesome new responsibility. For that reason, the current provisions of section 24 should be preserved, as is proposed in S. 2620.

Public Standing

Recent Court decisions [notably, EDF v. Costle 631 F. 2d 922 (1980)] have narrowly construed the standing of members of the public to initiate and participate in suspension and cancellation proceedings at the EPA. None of the three bills currently before Congress address the question of the public's right to participate in EPA's pesticide regulatory process. Our recommendation is that FIFRA be amended to assure public participation at each stage in the regulatory process. This should include: a notice and comment period prior to registration of a pesticide, as well as an opportunity to object to the agencies failure to cancel or suspend a pesticide, or to sufficiently restrict its uses, following an RPAR (Rebuttable Presumption Against Registration) proceeding. Along with the right to participate in such proceedings, the public must be provided with access to the data which federal decisionmakers use in making their decisions.

Confidentiality of Data

Section 10 (d) of FIFRA governs the confidentiality of data submitted by registrants to the EPA. It was adopted by Congress in 1978 to clarify which data could be released to the public, and which would be withheld. The current law balances the interests of manufacturers with the interests of the public. First, it provides confidential treatment for four types of data: 1) manufacturing or quality control process; 2) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient; 3) the identity or percentage of any deliberately added inert ingredient; and 4) information concerning production, distribution, sale and inventories of a pesticide. (These types of data may be disclosed under exceptional circumstances).

Second, it provides for the release to the public of safety and efficacy data. Safety and efficacy studies rarely contain the above-described confidential data. This full disclosure policy for safety and efficacy data contains only one limitation, which prevents delivery of the data to multinational pesticide companies. The 1978 amendments permitted domestic pesticide companies access to safety and efficacy studies of others, because it recognized that U.S. patent laws and the exclusive use periods contained in Section 3 were sufficient protection for the submitters of such data.

S. 2620, which is based on H. R. 5203 replaces the simple release or do-not-release system with a complex system that governs who gets access, how they maintain copies, what can be published, and even governs methods of communication among scientists, and between scientists and courts. Those bills fundamentally ignored the protections offered by the patent laws, and section 3 exclusive use provisions. They instead seek to allow disclosure of data to the public without allowing disclosure to any pesticide producers. S. 2620 and H. R. 5203 do this by delegating the problem to EPA with a mandate to adopt regulations which achieve that result. The controls mandated by the bills will be burdensome, and will create a substantial obstacle for the flow of such studies through traditional scientific peer review, or to the public. Provisions which treat "innovative methods or technology" with special protections will require line by line scrutiny, and possible litigation, over every safety and efficacy study. These provisions, too, fail to consider the protections offered to such innovations by the patent laws, and substitute a broad secrecy plan instead.

The regulations will obviously be crucial in determining whether safety and efficacy studies will circulate among scientists and the public. S. 2620 omits "principles" governing adoption of the regulations contained in H. R. 5203. These principles may be of some value to the EPA and courts which must ultimately decide the crucial questions. Unfortunately, the pesticide industry has in the past demonstrated the willingness to use a multitude of legal challenges to block the release of safety and efficacy studies. Until recently, the 1978 amendments have been held up by unfounded Constitutional challenges. Now that the current law is being upheld, these bills and subsequent regulations may unleash a new wave of litigation that will block all data releases for years to come. That is one reason to leave section 10 unamended and give it a chance to work.

The Section 10 amendments represent a substantial retreat from the principle of open discussion of health and safety data. Pesticides are useful, but dangerous, toxic chemicals, Public acceptance of pesticide use must be founded on confidence in the regulatory program. More information, not less, builds such confidence and serves, in the long run, both industry and the public.

The Data Gap

Each of the three bills currently before Congress amend provisions of FIFRA relating to disclosure of safety and efficacy data, state authority to require such data, or both. They do not, however, address the data gap problem. The data gap refers to the fact that most pesticides now on the market have not been registered under current standards with full testing of their potential to cause cancer, birth defects, sterility, genetic mutations, and other chronic health effects. This is a result of USDA and EPA policies of grandfathering previously registered pesticides, along with EPA's failure to meet the five year goal set by Congress in 1972 to reregister all pesticides under current standards. Achievement of that goal is still not in sight.

The American Farm Bureau Federation, which is represented here today, complained about this problem last summer to the House subcommittee examining FIFRA amendments. The Farm Bureau pointed out that nearly all of agriculture's essential 150 pesticides have yet to be reregistered by EPA, and may take 40 more years to complete. Numerous Congresional investigations have also identified this crucial problem. [For example: see Subcommittee on Admin. Practice & Procedure, Senate Judiciary Committee (Dec. 1976); Subcomm. on Oversight and Investigations, House Comm. on Interstate and Foreign Commerce (Dec. 1978); GAO report on "Delays and Unresolved Issues Plague New Pesticide Protection Programs" (Feb. 1980).]

In addition to the absence of chronic effect safety testing, the EPA has now determined that hundreds of tests which were submitted in suport of registration are invalid, due to shoddy and possibly fraudulent laboratory work. Finally, the data gap continues to expand through the use of conditional registrations. Major FIFRA legislation should not neglect to compel an end to the data gap at the earliest possible time.

Other Isues

S. 2620 did not incorporate provisions of H. R. 5203 which provide important anti-retaliation protections for persons exercising their rights under FIFRA. We believe that those provisions should be included in FIFRA legislation, because the cooperation of persons working with these highly toxic chemicals is essential to any enforcement program. In addition, we have proposed an amendment to Section 16 of FIFRA to provide private citizens with a private right of action to enforce the provisions of FIFRA. In an era of shrinking enforcement resources at the EPA, private citizens can enforce FIFRA against lawbreakers under such a provision. Without such a remedy, violations of FIFRA will be uncompensated and undeterred.

We have also offered amendments concerning adoption of farmworker protection standards. Prior to 1972, FIFRA was primarily a labeling and packaging law. In 1972, Congess empowered the EPA to prevent unreasonable adverse effects on man and the environment. Yet, EPA has never made the transition from a labeling approach to a worker safety approach. It still relies on labels, not merely as one means to communicate safety standards, but as the only means to promulgate such standards. This narrow interpretation has resulted in an abdication of EPA's responsibility toward development of safety standards to protect farmworkers. One need only compare standards adopted by California to those of the EPA to see the degree of neglect which has occurred at the federal level. Farmworkers should have the same type of protection standards offered to other workers through the OSHA program. That is, rules must be promulgated that clearly delineate employer and employee responsibility, and which set permissible exposure limits for each pesticide in the workplace. If EPA cannot meet this responsibility, OSHA should be charged with responsibility to do so. Pesticides are necessary and important tools of agricultural production and pest control. They are, however, inherently toxic. Virtually everyone in the United States is exposed to pesticides involuntarily, through food, water, or the air. Tests indicate that all of us carry pesticide residues in our bodies. FIFRA is currently designed to balance the need for use of the chemicals with the need to protect health and the environment. Pesticide problems during the past 10 years, including sterility of workers, and contamination of water and milk supplies, indicate that these dual goals have not yet been achieved. Given these circumstances, the public's right to participate in FIFRA decisions, and access to data should be strengthened. Adequate safety and public confidence cannot be achieved unless the performance of the pesticide system is improved, and public participation is assured.

STATEMENT OF NATHAN J. KARCH,. PH. D.

Mr. Chairman, members of the committee, my name is Nathan J. Karch. I hold a Ph.D. in chemistry from Yale University, and I have postdoctoral training in toxicology, epidemiology, and biostatistics. I am a Senior Science Advisor at Clement Associates, a consulting firm that specializes in risk assessment, and I teach toxicology and epidemiology at Howard University. The views I present here today are my own and are not necessarily those of Clement Associates nor those of Howard University.

In my professional career, I have often addressed the issues of confidentiality of and public access to data under discussion today. At Clement Associates, I have worked on projects involving the assessment of the health and environmental risks of pesticides for government, pesticide manufacturers, environmental groups, and citizens exposed to pesticides. Before joining Clement, I was a staff member for toxic substances and environmental health at the President's Council on Environmental Quality. During that period, I directed the activities of the Toxic Substances Strategy Committee for over a year; one of the task groups of that committee addressed the issue of the treatment of confidential information on toxic substances. I have also served as staff officer to a committee of the National Academy of Sciences concerned with the use of scientific and technical information in decision making by the U.S. Environmental Protection Agency (EPA). I also worked for committees of the American Chemical Society on public policy, environment, and patents.

I am here today to discuss with you the importance of the information that would be covered by the proposed changes regarding innovative methodologies to Section 10 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This information is extremely useful in the scientific assessment of risk. I believe that this may be of help to you in deciding where to strike the balance between corporate and public interests and whether to extend the cover of confidentiality to innovative methodologies. I will also raise some practical problems that may arise from the current version of the amendments, if enacted, and that you may wish to consider in order to give guidance to EPA in implementing the changes, if enacted.

THE ELEMENTS OF RISK ASSESSMENT

Risk assessment is based on two types of evaluation: hazard assessment and exposure assessment. Hazard assessment involves the review of the inherent toxicity of a pesticide chemical or mixture, its degradation and metabolic products. It is important to review the identity and potential toxicity of each possible substance in a pesticide formulation and its fate in the body and in the environment. A hazard assessment also involves an evaluation of exposure levels, doses, and test conditions derived from available studies in animals, exposed humans, and other test species, such as bacteria.

Exposure assessment involves the characterization of the route, degree, duration, and frequency of exposure likely to occur in the population of interest, e.g., pesticide workers or consumers of pesticide-treated food crops. Also evaluated are the size of the population of concern and any special characteristics that may make individuals within the population particularly susceptible to the toxic effects of the pesticide chemical or mixture, its degradation products, or metabolites.

The results of a hazard assessment and an exposure assessment are combined to do a risk assessment, i.e., it is possible to estimate the degree to which the identified hazards will be realized in the population of concern. The goal of a risk assessment is a quantitative estimation of risk, but in the absence of reliable data, this often is difficult to achieve in a meaningful way.

A common task of risk assessment involves the detailed evaluation of reportedly conflicting data. Sometimes, it is relatively easy to resolve such apparently conflicting data. For example, in a hazard evaluation, a study in mice reported to be negative may be too insensitive statistically to detect the effect found in a much more sensitive study in rats. In such a case, there is no true contradiction between the studies because one was not powerful enough to detect what was seen in the other. Another example of easy resolution of apparently conflicting data is a case in which the actual test substance used in two studies differs in chemical purity, and the toxicity is associated with the impure substance but not the pure substance.

Sometimes, however, apparently conflicting studies are not easily resolved and a scientific judgment must be made about the relative strengths, power, or applicability of a particular study or method of measurement. This requires detailed information on study methods and measurements. Thus, whether evaluating a single study or resolving conflicting data, detailed information on methods and results should be widely accessible.

PROPOSED LIMITATION ON ACCESS TO DATA

It is evident that a new provision in FIFRA that would extend confidentiality to a new area and limit access to data on product chemistry, residue chemistry, and metabolism if the methods involved were "innovative" would have a profound effect on the assessment of risk. It would interfere with accurate calculations of exposure and risks. To date, the scientific procedures employed in risk assessment (and the interpretations of risk estimates) have been vigorously debated in the scientific community and in regulatory proceedings. Because each stage in the evaluation of hazard, exposure, and risks is attended by considerable uncertainty, the results may support a number of interpretations.

The public debate on these procedures and interpretations has led over the years to widely accepted (though not unanimously accepted) criteria for evaluation of cancer risks. Criteria for evaluating risks of reproductive impairment and nervous system damage are only now beginning to be intensively examined. Even as we increase our knowledge of cancer induction and development, the criteria for evaluation of cancer risks may also develop further. I believe that any limitation on access to data relating to the identity and potential toxicity of exposure to a pesticide, its metabolites, or degradation products would inhibit the extensive "peer review" on risk assessment procedures and criteria that is necessary for sound risk/benefit decision making.

PRACTICAL PROBLEMS

As a scientific consultant, I can see several practical problems that may arise in the implementation of the proposed amendment. First, it seems unreasonable to expect that a scientific consultant could have access to the data but could not freely share the data with a client. Because the data for a risk assessment often can be interpreted in different ways, the underlying assumptions are very important. I think it would be difficult to discuss these uncertainties and assumptions without disclosing the data sources to a client. Restricting access only to scientists is likely to pose this problem.

Second, risk assessment is an interdisciplinary task. I often require the advice of colleagues in related areas to assist me in interpreting the details of a particular study. This exchange between colleagues, which is essential in any such complex and developing area, would be hampered by the necessity to clear all parties before a discussion could take place.

Because the sanctions for disclosure are so severe, any scientist who undertakes an analysis of the data would take great care not to reveal the data to anyone else who is not cleared. This too would hamper fruitful exchanges between colleagues. Perhaps even more important is the problem of interpreting the meaning of the proposed language. I am familiar with the issues in this area, and I found it hard to follow. If enacted, this difficulty may add to the barriers that would keep fruitful scientific exchange at a minimum.

Third, I do not see how EPA scientists will easily interpret whether a significant modification in an innovative technology has been made. This will be a difficult decision for EPA. It will always be in the industry's interest to submit any modification in the event that another 5 years of confidentiality can be obtained. I think that there will be great pressure (by time constraints and limited resources in the Agency) to approve modifications and extend confidentiality for 5 more years.

Finally, I am concerned about the following hypothetical situation arising: a consultant worked for Shell in 1978; in 1982, this consultant is asked by the Environmental Defense Fund to review data submitted by Dow. Could this consultant then be challenged by Dow as a representative of a competitor? The proposed provision should not be used to prevent access by interested parties other than competitors. Restricting access in such a case would not necessarily eleminate the possibility of an unscrupulous consultant working for a series of manufacturers and sharing data with one or more of them. Any restriction on access should be placed upon the demonstration of undesirable activity and not upon the possibility of its occurrence.

SUMMARY

In summary, I believe that the proposed amendments to Section 10 to extend confidentiality to innovative methodologies are undesirable because they would frustrate public access to important data and hamper scientific discussions in a rapidly developing area of research. I am aware that one of the examples offered of innovative technologies is the use of radioactive labels in pesticide chemicals to trace their fate in the body or in the environment. The innovation of radiolabeling of chemicals for biological testing can be traced to extensive funding by the former Atomic Energy Commission and several institutes of the National Institutes of Health. As in other areas of science, major innovations have occurred as a result of both public and private funding. The area of environmental toxicology is rapidly developing, is widely supported by public funding, and has readily identifiable implications for public health. I believe that there is a strong public interest in not extending confidentiality to innovative methods.

I would be happy to answer any questions.

Statement of Stephanie Bower, Legislative Representative, United Farmworkers of America, AFL-CIO

I am pleased to speak to you today to address the issue of proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

We must say that the present bills, S. 2621 and 2620 present serious problems for the United Farmworkers of America, AFL-CIO. Until and unless these problems are resolved, we regretfully must oppose.

We must oppose S. 2621 and 2620 because they unfairly place the burden on the worker, consumer, and the public when it should be placed on those who produce the chemicals.

We are concerned that pesticide enforcement be transferred from EPA to OSHA. As Dr. Ephraim Kahn, consultant to the California Department of Health Services, told this Subcommittee in Sacramento at your September 4 hearing, the EPA has been weak in evaluating and controlling health hazards. It is totally lacking in orientation toward this issue and lacks staff acquainted with industrial hygiene and occupational medicine. "As a result, several hundred thousand agricultural workers . . . have been placed in second class status. They are exposed to highly toxic materials but are denied the safety protection accorded other workers under the Occupational Safety and Health Act."

S. 2621 and 2620 should mandate a private right to sue which we strongly support. In routine pesticide poisoning cases involving our workers, we will not be able to get EPA nor the state agricultural departments to effectively enforce the existing pesticide misuse laws. In routine pesticide misuse violations we have more faith in OSHA enforcement than we do in enforcement by State Agricultural Departments. In any case, we need access to federal court to deter serious violations of FIFRA by crop dusters and other pesticide applicators.

The UFW has a strong interest in reasonable access to information about pesticides for our farmworker members such as cancer incidence studies, genetic defect data, and exposure incidence data.

At present, this material is available to us by means of a simple request to EPA under FIFRA. The proposed amendments to Section 10 of FIFRA may cause us unnecessary and unreasonable difficulty in getting this information.

Our members are exposed to many pesticides in the course of the year. For example, tomatoes in California are treated with more than 60 different chemicals. A farmworker may work in three or four other crops during the year, and be exposed to many additional chemicals in each different crop.

Our members suffer from frequent acute short-term illness from exposure to pesticides in their daily work. They touch residues on plants, soil, irrigation pipes, and equipment. They often breathe in pesticides while working. They may be incurring long-term chronic damage from their constant exposures, leading to early disability, ill-health, and shorter lifespan. They are suffering damage to their unborn children. We oppose the proposed amendments to Section 10 because they are ambiguous, unclear and infringe upon our crucial right to know what hazardous substances we are exposed to in our work place.

Although we have problems in California with the state Department of food and Agriculture's enforcement of pesticide misuse laws, we recognize that CDFA has been more stringent than EPA in requiring pesticide producers to furnish health and safety data concerning the hazardous effects of pesticides on human beings and the environment.

We strongly reject the S. 2621 amendment to Section 24 which limits states' rights to set a higher ceiling than the federal government concerning the registration, sale and use of pesticides. Many of our farmworker children across this country die from accidental pesticide exposure. Some of these pesticides are for house and garden use. Under S. 2621 amendment, EPA can deny a state request for additional safety and health data if EPA finds this request is arbitrary or capricious or if comparable data is available elsewhere. To force states to seek EPA approval before they can seek such data does not make sense. California in the past restricted or banned pesticides after farmworkers died. Now California is routinely demanding more health and data than EPA requires in attempting to prevent harm before these deaths occur. We applaud this effort and therefore must reject the S. 2621 proposed amendment to Section 24.

Thank you very much for this opportunity to speak to you. I would be glad to try to answer your questions.

ORKIN PEST CONTROL,
Atlanta, Ga., June 28, 1982.

Hon. JESSE A. HELMS
U.S. Senate, Chairman, Committee on Agriculture, Nutrition, and Forestry, Dirksen Senate Office Building, Washington, D.C.

DEAR SENATOR HELMS: We are appreciative of the opportunity to present written testimony of this consequential legislation. Orkin is a division of the Rollins, Inc. As you may know, Orkin is the largest structural pest control and termite control company in the world. We operate in 42 states and the District of Columbia and in Mexico. We serve about one million customers in this country. Our interest in FIFRA is on behalf of our customers, our employees, and others in our industry who must abide by FIFRA and EPA regulations. We are a member of the National Pest Control Association, and in the main, are supportive of their positions regarding this legislation.

We have testified for and support pesticide legislation beginning with the amended FIFRA in 1971. We still support that sound legislation and common sense regulations are beneficial to the safe and effective use of pesticides. In 1972, we believe that the Senate Committee on Agriculture, Nutrition, and Forestry expressed the position that pesticide legislation would be limited to the state level. Committee Report S.R. 92-838 states:

". . . On this basis and on the basis that permitting such regulation (local) would be an extreme burden on interstate commerce, it is the intent that Section 24, by not providing any authority to political subdivisions and other local authorities of or in the states, should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulations of pesticides."

However, in the last two years there have been instances where townships and cities have begun to enact pesticide legislation. We feel that these instances were without the knowledge that the Congress intended to limit this legislative process to the state level. In both New York and Massachusetts, such local legislation have been reviewed by the offices of those state Attorney Generals, who concurred with the position set forth by our Congress in their legislative history report of 1972. As is well known, the physical, chemical and medical effect of pesticides is a complicated subject requiring great expertise in the determination of how they should be safely and benficially used.

As judgment in the pesticide application area is already established and experienced at the state level, we see them, as did Congress, as the logical body to consider, review and enact legislation. With the exception of a few large cities in our country, we seriously doubt that this level of expertise exists at the local township or county levels. Thus, this principle is established by the level of expertise which is required. It is understandable that there can be local restaurant ordinances or zoning ordinances or building codes. Such as these do have a degree of knowledge at the local level which permits the consideration and establishment of local ordinances. In pesticide application, however, there needs to be safety, benefit, and uniformity which can best be done at the state level.

We, therefore, support the amendments to Sections 24(a) and 26 in S.2621 that clarifies State authority by stating that a State shall not be deemed to include any of its political subdivisions or any agency thereof for the purpose of the authority for pesticide use regulations and their enforcement. This would not interfere with the State delegating responsibility for enforcement action to officials at less than the State level for carrying out State policies.

We further wish to request continuing support for state programs of training and certification. In keeping with the general principles established in our country and in these matters of civil law, we strongly support an education process as opposed to an enforcement process where punitive measures may be used to try to achieve compliance. Better training than punishment. In our opinion, enforcement is a measure to assure compliance rather than a process to apply punishment. In this, we certainly hope adequate funds equal to past allotments can be designated specifically for certification and training procedures to be carried out by the states. We do understand and support the principles that the states will provide matching funds to the extent of 50 percent of those provided by our Federal Government.

We wish to commend this Committee for its attention and support of FIFRA legislation. We believe that, primarily through the efforts of this Committee and its counterpart in the House, that EPA as a regulator for FIFRA is much more understanding of the needs for applications of pesticides to protect the food and fibers and structures of our nation.

Safe and sensible pesticide use contributes to the best and most abundant food supply of any nation in the world. This food supply must be protected and conserved from farmer's field to commerce to the householder's table. This Committee has contributed significantly to a balanced pesticide use position for protection of food, fiber and structure. For that, we are appreciative. We sincerely hope the influence of the Committee will continue to assist the Agency in correctly executing FIFRA. In addition, we feel that the cooperative arrangement between state officials and EPA officials, SFIREG, has also been a most helpful device to improve the understanding and cooperation of all involved in the use of pesticides.

We appreciate the opportunity to speak for our company and for others in the structural pest control industry regarding FIFRA legislative needs in this section of the Congress.

Sincerely,

R. M. Russell,
Vice President, Government Relations.

Orkin Pest Control,
Raleigh, N.C., June 25, 1982.

Re amendment to FIFRA H.R. 5203.

Hon. Jesse Helms,
U.S. Senate, Committee on Agriculture, Nutrition, and Forestry, Dirksen Senate Office Building, Washington, D.C.

Dear Senator Helms: During recent months the area of Central North Carolina has come under attack by the gypsy moths. This has created a great deal of concern among small towns and municipalities and some may be considering passing their own pest control laws.

When Congress passed FIFRA, it was my understanding they felt that a federal law and state laws were enough and that there should not be local pesticide laws.

To me, pesticide regulations at less than the state level of government will create confusion among users as to what is legal in use of pesticides in the areas in which he or she may live or serve as a business person.

I understand Senator Hayakawa is introducing an amendment that would clarify the provision. In my opinion, there is no need for local pesticide laws. The federal and state laws are quite sufficient and clearly defined.

Your support for H.R. 5203 is requested. We in the industry welcome your comments and support now and in the future.

Sincerely,

Steve Drennan,
District Manager,
Central North Carolina District.

Orkin Exterminating Co., Inc.,
Charlotte, N.C., July 1, 1982.

Hon. Jesse Helms,
U.S. Senate, Committee on Agriculture, Nutrition and Forestry, Dirksen Senate Office Building, Washington, D.C.

Dear Senator Helms: As a concerned Citizen and Licensed Applicator in the State of North Carolina, I would appreciate your support of the Attached Amendment H.R. 5203.

The State of North Carolina does a good job of enforcing the F.I.F.R.A. Act, as well as protecting the consumer. I feel any additional Laws or Regulations would be harmful and cumbersome for the Pest Control Industry as a whole.

I know I can count on your support.

Sincerely yours,

JACK MURPHY,
District Manager.

PROPOSED AMENDMENT

For inclusion in H.R. 5203 to amend the Federal Insecticide, Fungicide and Rodenticide Act.

SECTION 24. AUTHORITY OF THE STATES

I. amending subsection 24(a), page 64, line 13 and line 17, and page 68, line 3, after word "State" so as to read: "State but not a political subdivision of a State . . ."

II. adding a new subsection (5) on page 69 line 22 to read as follows:

"(5) For the purposes of this section, a State shall not be deemed to include any of its political subdivisions or any agency thereof."

SECTION 26. STATE PRIMARY ENFORCEMENT RESPONSIBILITY

I. adding a new subsection 26(d) on page 73, between lines 2 and 3 to read:

"(d) For the purpose of this section, a State shall not be deemed to include any of its political subdivisions or any agency thereof."

Need for this amendment

During 1981 and 1982 several States have taken action to pass responsibility for determining what pesticides and what uses are to be allowed by county and township levels of government. This proposed action includes policy decisions that differ from that of the State and other local levels of government within the State.

This promise of fragmentation of responsibility with a State for pesticide use policies endangers the public health and safety by increasing the difficulty of the pesticide user community to know what rules apply at what time and to whom. Pesticide regulations at less than the State level of government will create confusion among users as to what is legal in use of pesticides in the areas in which he may live or serve as a businessperson. Sharing of the financial burden of pesticide regulation appears to be one incentive for proposed State action to allow enforcement authority at lower levels of government. Without clarity of FIFRA on this subject, additional states can be expected to attempt to share direct responsibility and costs for pesticide regulatory action with local governments.

Control of pesticides is now provided by the U.S. Government and the fifty States and territories in a relatively uniform matter which is considered essential in the production, marketing and use of pesticides. Therefore, the U.S. Congress recognized and included in its deliberation, when FIFRA was amended by the 92nd Congress, that further regulation by sub units of State governments, including county and city governments, was not in the best national interest. Committee Reports S.R. 92-838 and H.R. 92-511 state clearly that the absence of language in FIFRA granting such authority at less than State levels of government displayed Congressional intent not to permit the regulation of pesticides by political subdivisions of States.

Without a clear provision in the Act to declare the intent of Congress on this matter, decision on it has become subject to individual State interpretation. This amendment is submitted to clarify the intent of Congress as expressed in the hearing record of this topic.

CIBA-GEIGY CORP.,
Greensboro, N.C., May 20, 1982.

Hon. JESSE HELMS,
U.S. Senate,
Washington, D.C.

DEAR SENATOR HELMS: Legislation is being drafted on FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) by your Agriculture Committee. I would like to outline briefly those Sections of the law we, at CIBA-GEIGY, feel are in vital need of amendment:

1. Sec. 3. Registration of Pesticide.

a. Fifteen years exclusivity of use of data—deletion of compensation—both effective September 30, 1978.

The Industry, with the Congress in agreement, has felt for many years that the data submitted by an original applicant for a new product registration should be protected from use by EPA to register another company's product containing the same active agreement. In 1972, FIFRA was amended to provide compensation for use of another's data. Compensating proved to be an inadequate solution. In 1978, FIFRA was amended to provide for a combination of 10 years exclusivity of data and 5 additional years of compensation. This was a big step forward but the bookkeeping and cost of the compensation portion hardly seemed efficient.

The present proposal is to allow 15 years exclusivity and eliminate compensation for those active ingredients registered after September 30, 1978. This we heartily support. Both EPA and Industry will benefit by this amendment.

b. New Uses. Data generated to amend a registration should also be subject to some form of use exclusivity. New use needs to be better defined. The House bill definition of "new use" fails to include "crop groupings." We feel this is important! If additional money and manpower are to be expended to develop scientific data to support new use tolerances, then data protection is justified. Expansion of uses for any given product is beneficial to a grower as it reduces his required inventory of pesticides. Data protection also provides us an incentive to develop data for minor uses; there is more assurance of, at least, a minimum return on investment.

We urge a "new use" definition that includes "crop groupings." We urge a period of exclusivity for data specifically pertaining to that "new use" of 15 years.

2. Sec. 10. Protection of Trade Secrets and Other Information Sec. 3(c)(2)(A) of FIFRA states that:

"Except as provided by Sec. 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision."

Limitations in Sec. 10 were very closely defined in 1978 and left very little which could be called "trade secret." How, and in what form, data should be made available after 30 days has not been established. Use of FOIA has been the instrument of data release by EPA.

Language in the House bill is a step forward in trying to accommodate two somewhat varying positions:

1. Industry's desire to maintain some control over vital data for a commercial product even after such data have been submitted to the EPA under FIFRA requirements. The objective is to prevent subsequent use of the data by a competitor in the U.S. or elsewhere for registration purposes.

2. The public's right to evaluate data, particularly in the area of health and the environment, when a need arises.

Although the House language leaves much to be desired, it is still a step forward from FOIA. We support this.

An amendment to Sec. 24(a) has been included in the House bill and is being actively pursued in the Senate. Recent actions by some states to require data over and beyond that required by the Federal statute has raised concern that such a trend could greatly reduce marketing on a national scale. This, in turn, has created a desire to define more clearly the right of a state to "regulate the sale and use of any federally registered pesticide or device in the state." Past history has shown that most states have recognized the necessity of basic uniformity in regulating pesticides. Problem areas have normally been resolved through the route of negotiation rather than by strict definition of law.

We support the principle of the proposed Sec. 24(a) amendment but would not like to see a Sec. 24(a) debate result in the loss of Sec. 3 and Sec. 10 amendments.

Amendments to Sec. 12 and Sec. 16 have been proposed in the House and are being pursued in the Senate. We believe that the goals envisioned by their advocates are covered by other laws and regulations and properly so. FIFRA is not the appropriate vehicle for their placement into law.

We hope that amendments to Sec. 12 and Sec. 16 do not appear in the Senate Bill. We were pleased to see Sec. 16 wording deleted from the House language.

As to the amendments regarding SAP and the authorization for appropriations, we are in complete agreement with those.

This letter will be followed by amplification of our thoughts with proper staff members. We did want you to know of our concerns regarding FIFRA.

Yours very truly,

H. B. Camp,
Research and Development.

TERMINIX INTERNATIONAL,
Fayetteville, N.C., June 14, 1982.

Senator JESSE HELMS,
Senate of the United States,
Washington, D.C.

DEAR JESSE: It has recently been brought to my personal attention that many small towns are contemplating passing their own pesticide laws in reaction to the spread of the gypsy moth through their communities.

I am told by others familiar with this issue that local pesticide laws were intentionally not provided for in the FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) when it was passed by Congress because it was felt that the federal and state laws were entirely adequate.

My personal experience is that indeed the federal and state laws are quite adequate. In 1954 Cutlar Moore, a state senator from Robeson County, proposed legislation to provide Robeson County with a local county ordinance to regulate pest control operators. In reaction to this the pest control operators, the Department of Entomology at NCSU, and the N.C. Department of Agriculture countered with a statewide Structural Pest Control Law in the belief that these matters were better handled on a state level.

Twenty-eight years later this law is still in effect. It has resulted in a model enforcement agency which has done the citizens of our state a good job protecting the consumers of the pest control services.

In addition there is a high level of cooperation between the state authorities and the pest control operators. Any further division of this type of authority would be most regrettable, because there are not enough competent personnel in the field of enforcement to spread among every political subdivision in this country.

Therefore I am heartily requesting that you support the addition of (d) in Section 26 in H.R. 5203 which reads as follows:

"(d) State authority to regulate sale, application and use of pesticides under provisions of this Act shall be vested exclusively in State and territorial governments but not subdivisions hereof."

Please do what you can on this matter.

Thank you.

D. R. NIMOCKS.

NATIONAL ASSOCIATION OF COUNTIES,
Washington, D.C., June 10, 1982.

Senator JESSE HELMS,
Russell Senate Office Building,
Washington, D.C.

DEAR SENATOR HELMS: As you are aware, the Committee on Agriculture, Nutrition, and Forestry will soon have under consideration the reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The National Association of Counties (NACo) is very concerned about this issue and in particular the amendments being proposed by Sen. Hayakawa.

We are particularly concerned that despite the current rhetoric on "New Federalism" the Congress will enact these provisions which could hamstring the ability of state and local governments to design a pesticide program to meet the needs of their citizens. For the last decade the right of states to require information and impose standards beyond the federal requirements has been embodied in FIFRA. The current administration, and all administrations of the last decade, have supported Section 24(a) of FIFRA as written. The law has worked well and the case for changing its provisions in so radical a manner has not been made.

From our vantage point it appears that support for the concept of states rights ebbs and flows depending on the effect on an industry's economic position. Where an industry feels that they will benefit from state regulation over federal regulation they are ardent states righters. However, should a state reflect the desires of its constituents by imposing a regulatory scheme more stringent than the federal scheme that same industry will cry out for federal pre-emption and regulation.

If adopted as proposed, Sen. Hayakawa's amendments would take us yet another small step down the road toward centralized government control, a step we strongly urge you not to take.

Sincerely,

Mark I. Croke,
Legislative Representative.

The National Association of State Departments of Agriculture,
Washington, D.C., April 1, 1982.

Hon. Jesse A. Helms,
Chairman, Committee on Agriculture, Nutrition and Forestry,
U.S. Senate, Washington, D.C.

Dear Mr. Chairman: Our Association has learned that the FIFRA reauthorization legislation may be taken up by the Committee on Agriculture, Nutrition and Forestry following the Easter Recess. The Committee will be asked to consider a number of substantive changes in the current statute, including a proposal to amend FIFRA Section 24(a) and restrict the authority of States to regulate pesticides within their own borders. Specifically, the proposal would make the U.S. Environmental Protection Agency the final arbitor of what types of data a State could require for purposes of State registrations.

The Association strongly opposes any change in FIFRA Sec. 24(a). When Congress enacted Sec. 24(a) in 1972, you recognized that special local conditions sometimes pose health and safety questions that can only be answered by requesting additional data not already on file with EPA. In general, States have used this discretionary authority very sparingly. In fact, many States have never had occasion to request additional data, because the need has never, as yet, arisen. The provision worked smoothly and without controversy until recent months, when one State began to issue routine requests for additional data that some manufacturers view as excessive and unnecessary.

We acknowledge that a problem exists in California. Efforts are now underway to ease or resolve the problem in California, and progress is being made. Meanwhile, other States continue to cooperate with industry and user groups to expedite State registrations. We are determined to keep data requests at the bare minimum consistent with public safety. Amending Sec. 24(a) is unnecessary, because the California situation is being improved; and it is unfair, because it jeopardizes the interests of 49 States in order to legislate a change in one State.

The Association believes that a larger principle is at stake in the Section 24(a) dispute. The proposed amendment gives EPA a veto over the operation of State pesticide registration programs. This is another example of Federal pre-emption of powers and responsibilities previously exercised at the State level. Federal encroachment on State and local prerogatives has already gone too far. We hope you share our conviction that the public interest would be better served if the States were given more responsibilities, not less.

There are other reasons why we oppose any weakening of State pesticide programs under FIFRA Sec. 24(a):

The proposed amendment puts EPA in the difficult position of having to referee between States and the industry and intrude into a decisionmaking process that exclusively involves State and local health and safety considerations. The proposed amendment includes provisions for judicial review that will increase the amount of FIFRA litigation that is already clogging the Federal courts. The cost of this litigation is ultimately passed back to pesticide users in the form of higher prices.

Finally, the proposed amendment will require each State to draft new regulations and establish new regulatory procedures that will be more cumbersome and time-consuming than the very simple and inexpensive procedures now operative in most States. This regulatory change will mean higher registration fees which, in turn, will be passed back to the consumers.

The Association looks forward to assisting you in any way we can as you begin the difficult process of reauthorizing FIFRA. Once again, we respectfully ask your support for maintaining Sec. 24(a) without change. Enclosed, for your information, is a copy of a recent policy resolution which states our position of no change in Sec. 24(a) and pledges our assistance in resolving any problems relating to State data requests.

Yours very truly,

James B. Grant,
Executive Secretary.

Enclosure.

NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE: POLICY NO. PI-17

FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA) REGULATIONS

The U.S. Environmental Protection Agency, in the administration of FIFRA Section 24(a), has set minimum standards for the regulation of pesticides. Such minimum standards meet the specific needs and expectations of each and every State.

Resolved, that the National Association of State Departments of Agriculture, meeting in Boston, Massachusetts, on September 23, 1981, opposes changes in FIFRA Section 24(a), which would reduce the ability of State to respond to pesticide regulatory needs, but pledges its support through the NASDA-EPA Task Force to work with all affected parties in resolving the current problem relating to requests by States for data on Federally registered pesticides.

WASHINGTON STATE PEST MANAGEMENT ALLIANCE,
Tacoma, Wash., June 15, 1982.

Re amendments to FIFRA.

Senator JESSE HELMS,
Dirksen Senate Office Building,
Washington, D.C.

DEAR SENATOR HELMS: We have admired your leadership in the Senate for many years. We have generally been supportive of your activity. We understand that you have authored a bill, S2620, regarding amendments to FIFRA. Generally, we feel that your amendments are good.

We, however, have seen the amendments to FIFRA by S.I. Hayakawa (S2621). Senator Hayakawa's bill adds one phrase that would solve many problems in the industry.

In Section 24-A, Senator Hayakawa has added the phrase, "a state, not a political sub-division of a state, . . ." can regulate pesticides.

In the state of Washington and throughout the Pacific Northwest, several small towns, counties and cities have taken it upon themselves to try to regulate pesticides. Some have even written ordinances that prohibit the use of herbicides in their watershed areas and in the city limits.

The watershed areas are not owned by the town, but are owned by private individuals. This deprives the individuals of property rights. It makes it impossible for them to manage their properties for forest and farm production. Furthermore, it prevents such agencies as Bonneville Power, Puget Power, and Burlington Northern Railroad to manage rights-of-way. I shall include two such ordinances passed by the town of Index, Washington, demonstrating the problem.

Furthermore, at least one small business in the state of Washington was nearly bankrupt by King County in such an action. The court costs to defend this small business exceeded $200,000. The gross revenues of the business in any year did not exceed $800,000.

Surely you can see the problems involved by sub-state political sub-divisions in trying to regulate pesticides. A similar case would be a doctor having to license as a physician in every county or every town in the area. It just simply is not practical or possible.

We would appreciate your support in our efforts of solving this problem. If we can be of further help, please do not hesitate to contact us.

Sincerely,

JAMES R. ELY, *President.*

TOWN OF INDEX

INDEX, WASHINGTON

ORDINANCE NO. 192

AN ORDINANCE PROHIBITING THE USE OF PHENOXY HERBICIDES IN THE TOWN OF INDEX AND SETTING PENALTIES FOR THEIR USE.

WHEREAS, the Town of Index is a geographically confined Town and various rights-of-ways pass within close proximity of residences, food serving establishments and the Index school, and most residents choose to practice organic gardening methods.

NOW, THEREFORE, be it ordained by the Town Council of Index:

Section I. Purpose and Authority. Under the authority of the state constitution and other applicable law, and for the purpose of protecting the health and welfare of its' citizens, this ordinance is enacted to establish that certain acts constitute offenses against the health and welfare of its citizens, and to establish penalties for such offenses.

Section II. Because we consider the use of phenoxy herbicides to be a hazard to the health of our citizens, and therefore a public nuisance, the commercial use of these substances in the Town of Index shall be illegal from this time on.

Section III. Any persons, corporations, businesses, governmental agencies, or units of government violating this ordinance or authorizing the violation of this ordinance shall be upon conviction thereof fined ($500.00) five hundred dollars and costs of prosecution.

Section IV. Enforcement. This ordinance shall be enforced by the Town Mayor, Town Marshal or his Deputy.

Section V. Severability. If any section, subsection, paragraph, sentence, clause or phrase of this ordinance is declared unconstitutional or invalid for any reason, such decision shall not affect the validity of the remaining portions of this ordinance.

Section VI. This ordinance shall be in full force and effect after its passage by the Town Council, approval by the Mayor, and posting in the Town.

Dated this 20 of April, 1982.

APPROVED:

Mayor, Town of Index

ATTEST:

Town Clerk, Town of Index

BEST COPY AVAILABLE

TOWN OF INDEX

INDEX, WASHINGTON

ORDINANCE NO. 193

AN ORDINANCE PROHIBITING THE USE OF PHENOXY HERBICIDES IN THE TOWN OF INDEX WATERSHED AND SETTING PENALTIES FOR THEIR USE.

WHEREAS, the water supply of the Town of Index is of such a purity that it needs no treatment of any kind to be fit for human consumption.

WHEREAS, RCW 35.88 gives the Town the authority to protect the water supply for the Town and to keep it free of pollution.

NOW, THEREFORE, be it ordained by the Town Council of Index:

Section I. Purposes and Authority. Under the authority of Chapter 35.88 RCW and general police powers granted by the state constitution and other applicable law and for the purposes of preserving and protecting the water supply of the Town of Index and in order to prevent pollution of the Town's water supply, this ordinance is enacted to establish that certain acts constitute offenses against the purity of the water supply of the Town of Index, and to establish penalties for such offenses.

Section II. Because we consider the use of phenoxy herbicides to be a hazard to the health of our citizens and therefore a public nuisance, the commercial use of these products in our watershed (shown on the attached map) shall be illegal from this time on.

Section III. Any persons, corporations, businesses, governmental agencies, or units of government violating this ordinance or authorizing the violation of this ordinance shall be upon conviction thereof fined ($500.00) five hundred dollars and costs of prosecution.

Section IV. Enforcement. This ordinance may be enforced by the Town Marshal, his Deputy, and/or by special police who shall be appointed by the Mayor. Any special police so appointed shall, after taking oath, have the powers of constables and may arrest with or without warrant any person committing any offense declared by law or this ordinance against the purity of the water supply of the Town of Index. Every such special police person shall when on duty, wear in plain view, a badge or shield bearing the words "special police" and "Index".

Section V. In addition, this ordinance may be enforced in the manner set forth in Chapter 35.88 RCW for abating, prosecuting or enjoining a nuisance.

Section VI. Severability. If any section, subsection, paragraph, sentence, clause or phrase of this ordinance is declared unconstitutional or invalid for any reason, such decision shall not affect the validity of the remaining portions of this ordinance.

Section VII. This ordinance shall be in full force and effect after its passage by the Town Council, approval by the Mayor, and posting in the Town.

Dated this 20 of April, 1982.

APPROVED:

BEST COPY AVAILABLE

WASHINGTON STATE PEST MANAGEMENT ALLIANCE,
Tacoma, Wash., June 15, 1982.

Re S2621, amendments to FIFRA.

Senator S. I. HAYAKAWA,
Dirksen Office Building,
Washington, D.C.

DEAR SENATOR HAYAKAWA. The members of Washington State Pest Management Alliance express our support to you for your amendments to FIFRA.

We are especially interested in Section 24-A and the phrase, "a state, not a political sub-division of a state . . ." can regulate pesticides.

In the state of Washington, indeed throughout the Pacific Northwest, political subdivisions such as counties, cities, and even communities have created serious problems in the use of pesticides by writing ordinances against such uses in their political sub-divisions. I shall enclose a sample ordinance from a little town here in Washington, population of about 200, by the name of Index, Washington.

Index, Wasington has stopped the use of pesticides in the watershed area around Index. Index does not own the property, in fact the property is owned by private concerns. These private individuals cannot even manage their own property in accepted and safe forest management techniques because of this ordinance. In addition to that, such agencies as Bonneville Power Administration, Puget Power, and the Burlington Railroad, cannot manage the rights-of-way through the town of Index or through the watershed area because of this ordinance.

Clearly the ordinance is illegal, and we are going to have to try to change the minds of the people in the town of Index. Any time this happens, divisiveness occurs, enemies are made, and problems are created. With the wording of your bill, the temptation of the sub-state political sub-divisions is taken from them to regulate the use of pesticides.

Regulating the use of pesticides on a sub-state level would be like a physician being required to get a medical license to operate in each individual town or county. It just simply is becoming an unworkable problem. We applaud you for seeing the problem, and proposing a solution to the problem.

If we can help you in passing this bill, please do not hesitate to call upon us.

Sincerely,

JAMES R. ELY, *President.*

OREGON DEPARTMENT OF AGRICULTURE,
Salem, Oreg., June 23, 1982.

Senator JESSE A. HELMS,
Chairman, Committee on Agriculture, Nutrition and Forestry,
U.S. Senate, Washington. D.C.

DEAR SENATOR HELMS: Enclosed for your information is a copy of Resolution No. 79 adopted by the Oregon Board of Agriculture at its May 5-6, 1982 meeting. The resolution, which deals with HR 5203 and proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act, expresses the Oregon Board of Agriculture's opposition to Sections 4, 5, and 13 and urges removal of these sections from the bill. If removal cannot be accomplished, the resolution urges defeat of the entire bill.

I wish also to express our support for S. 2620 which proposes certain changes in Sections 3 and 10 of FIFRA, but does not involve any amendments to Section 24(a). We urge that Section 24(a) be retained as it is presently worded.

Sincerely,

LEONARD KUNZMAN,
Director.

STATE BOARD OF AGRICULTURE, SALEM., OREG., MAY 5-6, 1982

Subject: Federal Insecticide, Rodenticide and Fungicide Act.

Information: Whereas there is currently legislation in the United States House of Representatives, H.R. 5203 which makes amendments to the Federal Insecticide, Rodenticide and Fungicide Act;

Whereas Sections 4, 5 and 13 of the bill would be detrimental and very disastrous to Oregon agriculture especially in the growing of vegetable crops, fruit, grain, grasseed and other growing crops.

Resolution No. 79: Therefore be it resolved that the Oregon Board of Agriculture urge our Congressional Delegation to vote for the removal of these three sections (4, 5 and 13), and if unable to do so, vote to defeat the entire bill.

Action: Moved by: Edwin Gebhard.

Seconded by: Eileen Zielinski.

Action Taken: Passed.

WYOMING DEPARTMENT OF AGRICULTURE,
Cheyenne, Wyo., June 16, 1982.

Senator JESSE A. HELMS,
Chairman, Senate Agriculture, Nutrition and Foresty Committee,
Washington, D.C.

DEAR SENATOR HELMS: The Wyoming Department of Agriculture would appreciate this opportunity in making our position known, with regard to the Senate Hearings on FIFRA reauthorization.

It is our understanding that these hearings will focus on two bills, S. 2620 introduced by yourself and S. 2621 introduced by Senator Hayakawa.

S. 2620, although proposing certain changes in FIFRA Sec. 3 and Sec. 10, does not contain any amendments to Sec. 24(a) relating to a state's authority in regulating its own pesticide registration program. We have no objections to this bill, particularly Sec. 24(a), since it is consistent with our position, and appears to be in line with President Reagan's policy of allowing states to maintain their own programs with little of no federal intervention.

However, S. 2621 which gives EPA a veto over state data requests involving all pesticides is totally contrary to Wyoming's position.

It is our feeling that the introduction of this bill by Senator Hayakawa, was brought about by one state's request for additional data, that some chemical producers found objectionable. Why interfere in the programs of all states when the problem may only exist in one state?

The bill, besides over burdening EPA with decision making between states and chemical companies, also seriously affects the laws and regulations that states already have in force. Who can determine special local needs better than the states themselves. In Wyoming's case, we would have to propose new regulatory procedures to our own legislature, dealing with special local needs and pesticide product registration.

In closing, we feel this bill giving EPA veto power is another example of the federal government pre-empting the responsibilities of individual states. We are completely opposed to any part of S. 2621.

Again, we thank you for the opportunity to express our views on this matter. Your consideration of these comments is greatly appreciated.

Sincerely,

JOHN ORTON, *Commissioner.*

WASHINGTON FOREST PROTECTION ASSOCIATION,
Olympia, Wash., June 23, 1982.

Hon. JESSE HELMS,
Chairman, Committee on Agriculture, Nutrition and Forestry, U.S. Senate, Russell Senate Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: We have been following very closely the suggested amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Washington Forest Protection Association has been very much concerned with pesticide issues in Washington State for some years and even though we do most of our work through an outfit called Washington State Pest Management Alliance (WSPMA) we still follow those pesticide issues which impact us.

Obviously you are a busy man so I won't take up your time reiterating the forest industry position. Suffice it to say, we agree wholeheartedly with National Forest Products Association comments sent to you over the signature of Michael C. Ferrar of NFPA. We would like, however, to comment on two items that are especially important to us:

The concept of "frivolous" lawsuits is probably one of the most explosive issues of the FIFRA amendments. One of the founding principles of this country is the ability of any person or entity to have access to the judicial system. On the other hand, viewing the backlog of suits in state and federal courts, it is apparent that something must be done. As far as we can tell, citizens can bring suit in state court for injunctions and damages. Washington State has very specific statutes and an agency that deals with pesticide laws. Very clear penalties are provided for chemical misuse. Obviously, a legitimate citizen complaint has open access to the judicial system to seek relief when he/she feels wronged. We completely agree with NFPA that there is no need for a new, broad and undefined right to bring private enforcement suits into federal courts. Well established remedies for pesticide use violation already exist and have not been shown to be inadequate.

We urge you to very carefully look at this issue when it is brought up.

The second extremely important part of the FIFRA amendments is the limitation of specific state subdivisions from regulating the sale or use of any federally registered pesticides. This has been a larger problem in Oregon than Washington but we can see the handwriting on the wall. Anti-pesticide groups are small but extremely active and vocal people who can railroad anti-pesticide measures through county hearing processes. Forest landowners of Washington State may have land in just one county but many, including numerous non-industrial landowners, have land in two or more counties. Pesticide regulation development by individual counties would result in absolute chaos for forest managers in our area and, I assume, across the country. The Washington State Department of Agriculture in conjunction with Federal EPA has done an excellent job of regulating pesticide applications. We wish to underscore NFPA's support for keeping pesticide regulation at the state and federal level.

Pesticides are obviously an important part of the forest management game plan. We recognize the sensitivity of pesticide use and accept fair regulation but also want to go on record echoing the sentiments of NFPA by saying, "If it ain't broke, don't fix it." If you have any questions, please feel free to give me a call.

Warm regards,

STU BLEDSOE, *Executive Director.*

CALIFORNIA SEED ASSOCIATION,
Sacramento, Calif., May 13, 1982.

Re Federal Insecticide, Fungicide and Rodenticide Act, section 24.

Hon. JESSE HELMS,
Chairman, Senate Agriculture, Nutrition, and Forestry Committee, U.S. Senate, Dirksen Senate Office Building, Washington, D.C.

DEAR SENATOR HELMS: I would like to inform you of some of the difficulties we have experienced regarding the pesticide registration process in California.

Because of the excessive data requirements being imposed by the California Department of Food and Agriculture, many of our members and other agriculturists have suffered crop damage and economic losses when needed pesticides were not available.

Over eighty-five percent of requests for registration of pesticides in California are denied because of insufficent data. Because of these overly stringent regulations, chemical companies will only bother with California registration when there is a great demand for the material. Our members who produce seed are often hurt by the lack of needed pesticides. Although seed is a very important crop, it is grown in relatively small amounts and requires less pesticides than the major crops.

A good example of the problems we have encountered with California registration is our request for a Section 18 emergency exemption for the fungicide Ridomil. Onion seed growers were experiencing severe losses because of mildew infestations. Our Association applied for an emergency exemption for Ridomil in December, 1980. In July of 1981, we were informed that there was insufficient data to approve our request. We resubmitted the petition in December, 1981 and received our emergency exemption in February, 1982. From the time we applied for an emergency exemption to the time it was approved, fourteen months had passed.

We are not critical of the California staff for the delays in receiving our emergency exemption. The policies, not the personnel are to blame for the excess time it takes to register a product or receive an emergency exemption.

Amending Section 24 of the Federal Insecticide, Fungicide, and Rodenticide Act so all requests for additional data will be reviewed by the Federal government would be of great help in bringing a more effective system to California.

Your leadership in providing this change in the Act would be a great service to agriculture and deeply appreciated by the members of our Association.

Respectfully,

PAUL W. STEPHANY,
Associate Director.

EL TORO, CALIF., *June 23, 1982.*

Hon. S. I. HAYAKAWA,
Dirksen Senate Office Building,
Washington, D.C.

DEAR SENATOR HAYAKAWA: I am writing to ask your support and vote for H.R. 5203, amendments to the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

I believe that this is an important piece of legislation which will affect U.S. agriculture as well as the agrochemical industry. H.R. 5203 represents the best attainable compromise between a variety of interests including industry, agriculture, labor, and government. It contains safeguards necessary to protect one of the few truly innovative industries of today and will help ensure that American farmers will be given the tools necessary to protect the most important industry in our country.

I work in the agrochemical industry and believe that in this bill there are a number of particularly critical provisions including those in Sections 3, 10, and 24(a). Section 3 would extend from 10 to 15 years, a manufacturer's right to exclusive use of its registration data. Section 10 would establish an extremely reasonable system for the public to gain access to health and safety data in order to satisfy public health and environmental concerns. This section also provides protection for the manufacturer against harmful competitive disclosure. Section 24(a) would provide a clearer guideline for states such as California regarding the extent to which they may go beyond FIFRA in requiring registration data for certain pesticides. Such direction is important if manufacturers are to avoid a situation where fifty-one CDFA's must be satisfied before a product could be marketed. This provision can help to keep the cost of essential agrochemicals to reasonable levels for our farmers.

As one who is vitally interested in legislation in this particular area, I again solicit your support and vote for H.R. 5203 when and if it reaches the Senate for consideration. If I can be of any service to you in responding to questions on the bill from a constituent's point of view, please let me know.

Sincerely,

D. R. HARPER.

SOUTHERN LEGISLATIVE CONFERENCE OF
THE COUNCIL OF STATE GOVERNMENTS,
Little Rock, Ark, June 1, 1982.

Re FIFRA, preemption of State pesticide registration.

Senator JESSE HELMS,
U.S. Senate,
Washington, D.C.

DEAR SENATOR HAYAKAWA: As chairman of the Agriculture and Rural Development Committee of the Southern Legislative Conference (SLC), I ask that no legislation be introduced in the Senate which would change section 24(a) of the 1972 FIFRA. I refer specifically to language preempting a state's authority to register or request additional information on pesticides.

The Agriculture Committee of the Southern Legislative Conference of the Council of State Governments is composed of agriculture committee chairmen and other key legislators, and their staff aides of the State Senates and State Houses of Representatives in the 15 Southern States: Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia. I might also add that this conference has determined federal preemption to be such a prevasive issue that we have established a standing committee to monitor this problem. Rosters for both committees are attached as well as a summary of federal preemption legislation taken from the November '81 issue of our national publication, State Government News. As you can see, the pesticide issue was not overlooked.

Speaking on behalf of my committee, I urge you and members of Congress to reserve for each state the right to determine what is best for the agriculture and health needs of its citizenry. The federal government should not be in the business of attempting to commandeer the regulatory powers of the states. Because agricultural uses, densities and proximities differ widely from state to state and region to region, the states remain the most logical and effective unit of government accountability concerning pesticide use and application.

The federal government has traditionally been charged with the responsibility of establishing broad national goals for the states to follow. It has been left to the states to decide how best these goals can be achieved and implemented. Preemption in this case would deny a state's access to information needed to make a judgment on pesticide application. In my mind, it is simply inappropriate for the federal government to limit that implementation function which rests at the state level.

I suggest that the Congress retain section 24(a) of the 1972 FIFRA legislation.

Sincerely,

CHARLES R. MOORE,
Representative, Arkansas Chairman.

Enclosure.

PREEMPTION THREATENS STATE AUTHORITY

(By Helena Sims and Laura Brown)

State authority to regulate usury rates, pesticides, and other matters is threatened by legislation under consideration by Congress.

The proposals would shift to the federal government state authority to regulate or deregulate key agricultural and business interests. This could pave the way for making sweeping regulatory changes in one arena instead of 50.

On Oct 11, the Executive Committee of The Council of State Governments adopted a resolution opposing federal preemption of state authority, unless requested by the states themselves. In particular, the resolution opposes preemption of state authority to regulate "pesticide and plant pest control, cable television, and intrastate communications, hazardous materials transportation, usury, and standby petroleum allocation and prices."

A partial list of preemptive federal legislative proposals and their status is outlined below:

Pesticide control—Draft legislation being discussed by a House subcommittee would restrict a state's latitude in registering and requesting information about pesticides. The Environmental Protection Agency (EPA) could deny a state's request for additional health and safety data from a pesticide manufacturer. Further, a state would not be permitted to delay basic registration of a pesticide pending submission and review of data. The House Agriculture Subcommittee on Department Operations, Research and Foreign Agriculture is working on a compromise position prior to introduction of pesticide legislation. The Senate is awaiting House action.

Usury ceilings—Four bills awaiting committee action would preempt state authority to set usury rates. The bills propose different methods of preempting state usury ceilings on different types of loans. Two bills would abolish usury ceilings altogether for business, agriculture and consumer credit transactions (S. 1406 by Sen. Richard Lugar, R-Ind., and H.R. 2501 by Rep. John LaFalce, D-N.Y.). Two identical bills would establish federal ceilings for a broad and vaguely defined group of other loans (S. 962 by Sen. Dale Bumpers, D-Ark., and H.R. 3172 by Rep. William Alexander, D-Ark.). All bills are awaiting action by banking subcommittees.

Plant pests—An amendment proposed to the 1981 Omnibus Farm Bill (S. 884) in response to the recent medfly infestation in California would give the secretary of the U.S. Department of Agriculture (USDA) emergency authority to take action against plant pests that threaten crops. It would give USDA the right of entry to apply treatments to suspect properties (now up to the states), authorize USDA to quarantine produce and fields believed infested, and give USDA authority over the intrastate, in addition to interstate, transportation of produce. It does not make clear whether the state or the federal government would be responsible for the cost of any spraying or other USDA-initiated action.

The amendment was offered by Sen. S. I. Hayakawa, R-Calif. As of mid-October, it appeared doubtful that the provision would be included in the House-approved version of the farm bill, but it could resurface in conference committee.

Hazardous materials transportation—Legislation amending the Hazardous Materials Transportation Act of 1974 would require state and local regulations to be consistent with federal requirements. State and local governments would retain primary responsibility to respond to emergencies involving hazardous materials.

No date has been set for floor action on S. 960, sponsored by Sen. Howard Cannon, D-Nev., which was reported on May 15 by the Senate Committee on Commerce, Science and Transportation.

Petroleum controls—Legislation in both houses of Congress would extend the president's emergency authority to preempt state and local programs for allocating energy resources which expired on Sept. 30 with the 1973 Emergency Petroleum Allocation Act.

President Reagan opposes the bills, claiming the free market would allocate petroleum adequately without government intervention. The Senate Energy Committee on Oct. 1 reported S. 1503, sponsored by Sen. James McClure, R-Idaho. On the House side, H.R. 4314, sponsored by Rep. Thomas Tauke, R-Iowa, is awaiting markup by the Energy and Commerce Subcommittee on Fossil and Synethetic Fuels.

Cable television—Language which would have preempted state and local authority over cable television was stricken from S. 898 by an amendment by Sen. Barry Goldwater, R-Ariz., which was accepted 59-34 on Oct. 6. There is speculation, however, that the issue may surface again in other Senate legislation. The proposed legislation to amend the Communications Act of 1934 (S. 898) would have deregulated the cable television industry and preempted state and local authorities from regulating rates and enforcing existing franchise agreements. A further provision would have given the Federal Communications Commission statutory authority to set ceilings on franchise fees paid by a cable company, thereby potentially limiting state and local tax revenues. In addition, the legislation would have placed intrastate telecommunications toll service under federal rather than state jurisdiction.

Other—Not all preemptive activity is in the congressional arena. The U.S. Department of Commerce recently proposed and later withdrew regulations which would have allowed the federal government to override some state coastal zone management policies. Under the proposed regulations, the federal government could have excluded states from participating in decisionmaking about oil and gas leases in the outer continental shelf. After encountering stiff opposition from many coastal states and environmental groups, the Department of Commerce withdrew the regulations two weeks before their Oct. 16 effective date. In addition, the House Committee on Merchant Marine and Fisheries passed a resolution on Oct. 6 disapproving the regulations. A two-house veto of any proposed regulations was provided for in 1980 amendments to the Coastal Zone Management Act. The Department of Commerce is drafting new regulations.

In approving the preemption resolution, CSG's Executive Committee took a firm stand against unsolicited preemption of state authority. In accordance with a directive in the resolution, the CSG Washington Office will continue to follow congressional and executive agency proposals and will keep state officials updated and apprised of any new preemptive developments.

INTERNATIONAL LONGSHOREMEN'S AND WAREHOUSEMEN'S UNION,
Washington, D.C., June 22, 1982.

Hon. JESSE HELMS,
Chairman, Senate Committee on Agriculture, Nutrition, and Forestry, Russell Office Building, Washington, D.C.

DEAR SENATOR HELMS: I would like to submit for the Committee's record the views of ILWU on the Federal Insecticide, Fungicide, and Rodenticide Act and the amendments to it now under consideration in the form of S. 2620 and S. 2621. Since other expert witnesses have submitted extensive oral and written testimony on the various aspects of this issue, our statement will be confined to those provisions of the law which we consider particularly important.

ILWU represents approximately 13,000 longshoremen on the West Coast, Alaska, and Hawaii, and about 20,000 agricultural workers in Hawaii. Many of these workers are in direct contact with agricultural produce in the process of cultivation, processing and transportation on a regular basis. We therefore have a vital interest in the careful and thorough regulation of commercial poisons.

Our view is that FIFRA should be reauthorized; and that it should be amended in no way that further restricts non-federal access to safety and health data or denies the worker's legal rights of judicial protection. Any legitimate problems with the Act that may exist from the point of view of manufacturers or employers can be solved administratively; and legislative emphasis on the public and workers' safety should be, if anything, increased, not diminished.

It has been claimed by many conservatives that state and local authorities have a far better grasp of problems and priorities in their jurisdictions than do distant federal bureaucrats in Washington. But the approach of the "New Federalism" is curiously absent from the legislation now being supported by industry critics of FIFRA. In the instance of a program in which a state is currently allowed to go beyond a federal agency in its efforts to provide for the public and workers' health, it appears that the special interest and expertise of the state is not desirable. S. 2621 in its present form would make it extremely difficult for states to secure scientific data in connection with newly registered agricultural pesticides, primarily by establishing a "special local concern" criterion and by forcing EPA to judge whether a state request for industry data is "arbitrary or capricious."

To longshoremen and agricultural workers, however, the states' effective authority to obtain such data is absolutely essential. In California, this is borne out not just by theory but by the most immediate of circumstances. The number of physician-reported pesticide poisonings of workers statewide had doubled over the last eight years, and new situations of harmful worker exposure are constantly arising. As a result of the Medfly infestation, for example, ILWU longshoremen have been embroiled for several months in a dispute over the use of ethylene dibromide, a highly toxic fumigant. Proper regulation of workplace exposure to EDB has resulted solely from the initiative of state agencies—including the California Department of Food and Agriculture, which under FIFRA was able to conduct the necessary research on this chemical.

Similarly, ILWU agricultural workers on Hawaii's pineapple plantations are frequently exposed to many pesticides, including dibromochloropropane (DBCP) and EDB. It is essential that the state retain its authority to closely monitor the pesticides used in this and other tropical crop industries which are unique to Hawaii among the 50 states—particularly at a time when, as the General Accounting Office has confirmed, EPA investigation and enforcement of the law is already highly deficient.

Conservative critics of FIFRA have also shown a double standard in connection with the right of the worker to sue his employer for damages and injunctive relief. While manufacturers of pesticides are conspicuously guaranteed treble damages and attorney's fees in S. 2620 for illegal leakage of data, the bill contains no provision providing the worker's right to sue in federal court for mere injunctive relief against illegal exposure. The patent injustice of this requires no further comment. We merely state our strong support for the worker's right to sue for both relief and adequate damages.

Along the same lines, we also strongly urge that a specific remedy for redress be provided for workers who are discriminated against by their employers for exercising their rights under FIFRA. The language adopted for this purpose in H.R. 5203, the current House bill reauthorizing FIFRA, would satisfy this crucial need.

S. 2620 would exempt a substantial portion of safety and health data from public access under a new category of "innovative methods of technology." Apart from improperly precluding the vital process of scientific peer review, this would allow an unknown volume of crucial data to be virtually withheld simply because it can be related in some way to new industrial processes. Patent law and its exclusive-use provisions already provide adequate protection for trade secrets that would fall into this category. Even under FIFRA's current language, moreover, Congressional investigations have shown that inadequate and inaccurate industry data on new pesticides is submitted to EPA and withheld from public scrutiny. The purpose of FIFRA to effectively examine and screen dangerous poisons would be fundamentally compromised by this amendment.

For these reasons, ILWU opposes S. 2621 and urges that S. 2620 be amended to assure the worker's full right to sue for injunctive relief and damages; to provide a clear worker's remedy against discrimination by employers; and to delete the section on "innovative methods of technology."

Thank you for this opportunity to express our views on this important issue.

Sincerely,

MIKE LEWIS,
Washington Representative.

Alliance for Food and Fiber,
San Mateo, Calif., July 14, 1982.

Hon. **Jesse Helms,**
Chairman, Senate Agriculture, Nutrition, and Forestry Committee,
Russell Senate Office Building, Washington, D.C.

Dear Senator Helms: I would like to express my support of S 2621 to amend Section 24a of FIFRA. In particular, I support that section of the amendment which restricts to states, but not political subdivisions, the power and authority to regulate pesticides.

The Alliance for Food and Fiber is a consortium of major agricultural trade associations, including Farm Bureau, Western Growers Association, California Cattlemen's Association and a number of other groups representing a wide range of commodities. The purpose of the Alliance is to conduct an on-going public education program on the issue of crop protection chemicals.

It is clear that the intent of the legislative history of FIFRA is to prohibit the adoption of uneven regulations within a state as adopted by individual counties or other subdivisions.

California is a textbook case for attempts to regulate pesticides at other than the state level. Examples of politicial-judicial confusion arising from the adoption of pesticide regulations by political subdivisions include:

Trinity County: Earlier this month the California Department of Food and Agriculture filed suit against the county because of its adoption of two herbicide regulations. The first is a prohibition against the spraying of phenoxy herbicides. The second is a law requiring a county permit for the use of hazardous substances, above and beyond that required by the state. The effect is nothing short of a ban on the use of many useful agricultural and forestry tools. The CDFA has charged that the authority to regulate pesticides rests with the state and that the county agricultural commissioner is an agent of the state, not the county per se, and must therefore state regulations.

Mendocino County: The County Superior court has ruled against a ban on the aerial application of phenoxy herbicides. The court stated that state regulations perempt locally-adopted laws.

In other counties asked to vote on adopting more restrictive pesticide laws the following has been the result:

Humboldt County: In 1980 voters decisively defeated an initiative that would have outlawed the aerial application of phenoxy herbicides. Nevertheless, the financially strapped timber community was forced to foot the bill for this election.

Siskiyou County: On June 8, 1982 an initiative that would have specifically mandated that the county duplicate pesticide water monitoring services already required and performed by the State Water Quality Control Board was soundly defeated. This initiative had no other purpose than the duplication of services with no additional benefits, but considerable extra costs—to be paid for by county taxpayers.

Locally adopted regulations often affect areas much greater than their political boundaries suggest. For instance, had the counties of Santa Clara and Santa Barbara successfully adopted "no spray" laws for the eradication of the medfly and gypsy moth, respectively, hundreds of thousands of agricultural, and residential, acres in surrounding communities, and eventually the entire state, would have suffered.

If state pesticide regulations are not sufficient enough for one particular county, they are not sufficient enough for *any* county. Therefore, one political entity should be empowered and held responsible for pesticide regulations, and, as intended by FIFRA, this power should remain with the states and no other political subdivision.

Sincerely,

Pamela Jones, *Director.*

California Farm Bureau Federation,
Sacramento, Calif., June 17, 1982.

Hon. **Jesse Helms,**
Chairman, Senate Agriculture Committee,
U.S. Senate, Washington, D.C.

Dear Senator Helms: Senate Bill 2621 has been introduced to modify the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). We support the amendment to Section 24, Subsection (b), Subparagraphs (i) and (ii). We believe this amendment will limit arbitrary and capricious actions by a state.

In California, we found that while 500 products were registered by the California Department of Food and Agriculture in 1981, over 270 products were denied state registration. We understand many, if not all, were federally registered.

We believe the Environmental Protection Agency was established to set uniform tests and to determine the potential risk of pesticides to human health and the environment. Otherwise, we could have fifty states requiring different information and setting different standards at their whim. We do not dispute that states have a responsibility to insure the safety of our citizens. However, arbitrary and capricious action can effectively eliminate or, at the very least, seriously delay the availability of our chemical tools. This is a luxury we cannot afford in agriculture.

Finally, we urge your support of Senate Bill 2621. It should limit arbitrary and capricious actions by a state and provide a balanced approach.

Sincerely,

HENRY J. VOSS, *President.*

ELANCO PRODUCTS CO.,
Indianapolis, Ind., July 20, 1982.

Senator JESSE A. HELMS,
Chairman, Committee on Agriculture, Nutrition, and Forestry,
Dirksen Senate Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for our company's views on the issue of "innovative methods and technologies" under the data disclosure provisions of Section 10 of FIFRA.

Although there are standard guidelines for the information required for the registration of a pesticide, the techniques and methodology employed in developing the required information can be unique. For example, detailed information must be developed on the fate of a pesticide in the environment including its metabolism degradation and eventual dissipation in soil, plants, water and animals. Many times analytical methodology must be developed which is capable of measuring the pesticide or its metabolites at parts per billion levels in complex media. The development of the methodology often involves commitment of resources many-fold greater than the resources needed for making the measurements per se. Stated in other words, it would be relatively straight forward for a second registrant to generate environmental fate data on a pesticide, or a chemically similar pesticide, if the metabolic and analytical techniques as developed by the initial registrant, are available to them.

There is also another aspect of the issue which is more of a concern to us for the future than the present. As you know, Elanco is a Division of Eli Lilly and Company and Lilly is deeply involved in the application and development of recombinant DNA technology. We may have the first recombinant DNA product offered for commercial use, human insulin. We can foresee that as this totally new and complicated technology is employed in pesticide research, there could be many instances where we will be vitally concerned about protecting that technology.

In summary, we believe industry must have a mechanism to protect data which is truly new and unique, protection not only from U.S. competitors, but protection from foreign interests anxious to exploit American technology.

Thank you very much, Mr. Chairman, for giving us the opportunity to present our thoughts to you.

Very truly yours,

VAUGHN D. BRYSON.

NATIONAL COTTON COUNCIL OF AMERICA,
Washington, D.C., July 9, 1982.

Hon. JESSE A. HELMS,
Chairman, Senate Committee on Agriculture, Nutrition, and Forestry,
Russell Senate Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: We appreciate very much this opportunity to express our views on proposed amendents to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In that regard, we respectfully request that this letter be included in the official hearing record.

The National Cotton Council is the central organization of the U.S. raw cotton industry, representing cotton producers, ginners, merchants, warehousemen, cooperatives, cottonseed crushers, and textile manufacturers from California to the Carolinas.

Our concerns as they relate to FIFRA have been well documented in a special briefing package entitled, "EPA's Farm Pesticide Regulations (A Regulatory Reform Priority)," which was earlier submitted to Vice President Bush's Regulatory Reform Task Force.

Over the past decade we have witnessed a dramatic reduction in the availability of new agricultural chemicals. For example, prior to the formation of EPA, some 700 new pesticides were developed each year. The number has now dropped to fewer than 25. In one recent year, only four new pesticides representing new chemistry were registered. Among the reasons: (1) overlapping and duplicative requirements aimed more at preventing rather than registering new pesticides, (2) establishment of certain criteria completely lacking in scientific basis, (3) rigid guidelines regarding test methodology and (4) skyrocketing costs associated with the overall demands of the regulatory process.

We believe EPA is well aware of these problems, and its efforts to address them have been extremely encouraging. However, we agree with you that basic changes in the Act may be necessary to further streamline the registration process and provide incentives for increased research and development of new agricultural chemicals.

This is essential if agriculture is to continue to meet the food and fiber needs of consumers at home and abroad. For this reason, we support passage of S. 2620, which you recently introduced and which is now pending before the Committee.

There is also a need to expedite the clearance of critically needed new materials at the state level. In some cases we have seen delays of up to a year or more. This seems unreasonable, given the fact these materials have been separately approved by EPA and determined to be safe and effective. The amendments proposed by Senator Hayakawa would address this by establishing guidelines and certain criteria for state registration and approval. We urge the Committee to favorably consider this approach as a means of eliminating what has become, in some instances, a regulatory maze aimed at preventing pesticide usage.

Finally, we would also like to take this opportunity to voice our strong opposition to possible amendments which would add a "private right of action" provision to FIFRA. As proposed by a variety of interest groups, such a provision would allow any person aggrieved by misuse of a pesticide to bring suit in any U.S. District Court against farmers and ranchers. We believe this provision is not only unnecessary, given other remedies in this Act and other applicable statutes, but it is a potential "Pandora's Box." Rather than enchancing protections under the Act, the practical effect will be to merely encouraging such suits. As such, farmers and others will be threatened with endless, costly and time-consuming litigation. Experience with similar provisions in other statutes (Farm Labor Contractor Registration Act (7 U.S.C. 2041)) only serves to underscore this point.

Again, we appreciate this opportunity to present our views, and we look forward to continuing to work with you and your staff on this and other issues of mutual concern.

Sincerely,

EDWARD BREIHAN, *President.*

97TH CONGRESS
2D SESSION

S. 2245

To amend and extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for two years.

IN THE SENATE OF THE UNITED STATES

MARCH 22 (legislative day, FEBRUARY 22), 1982

Mr. HELMS (by request) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To amend and extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for two years.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136w), is amended by striking "September 30, 1981" and inserting in lieu thereof the words "September 30, 1984".

SEC. 2. Section 31 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136y), is amended by adding at the end thereof the following new sentence: "There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1982, and ending September 30, 1983, $44,208,000, and for the period beginning October 1, 1983, and ending September 30, 1984, such sums as may be necessary.".

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97TH CONGRESS
2D SESSION

S. 2620

To amend the Federal Insecticide, Fungicide, and Rodenticide Act.

IN THE SENATE OF THE UNITED STATES

JUNE 10 (legislative day, JUNE 8), 1982

Mr. HELMS (for himself and Mr. HAYAKAWA) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982".

DEFINITIONS

SEC. 2. Section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act is amended—

(1) in subsection (ee) by striking out "or" immediately before clause (4) and inserting immediately before ": *Provided further,*" the following: ", or (5) using a

registered pesticide product in the formulation of another registered end-use product, or repackaging a registered pesticide product into another registered end-use product, unless such use is prohibited by the labeling"; and

(2) by adding at the end thereof a new subsection as follows:

"(ff) Pesticide product means a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed, sold, offered for sale, held for sale, shipped, or delivered for shipment in any State by a particular person.".

REGISTRATION OF PESTICIDES

SEC. 3. Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act is amended—

(1) by amending subsection (c)(1) to read as follows:

"(1) STATEMENT REQUIRED.—Each applicant for registration shall file with the Administrator a statement which includes—

"(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

"(B) the name of the pesticide product;

"(C) a complete copy of the labeling of the pesticide product, a statement of all claims to be made for it, and any directions for its use;

"(D) data as required by subsection (h) of this section with any trade secret or commercial or financial information, or innovative methods and technology marked as required by section 10(a) of this Act;

"(E) the complete formula of the pesticide product; and

"(F) a request that the pesticide product be classified for general use, for restricted use, or for both.";

(2) by amending subsection (c)(2)(A) to read as follows:

"(2)(A) DATA IN SUPPORT OF REGISTRATION.—The Administrator shall publish guidelines specifying the kinds of information which would usually be required to support the registration of a pesticide product and shall revise such guidelines from time to time. The Administrator, in establishing guidelines for data requirements for the registration of pesticides with respect to minor uses, and with respect to various types and classes of pesticides, shall make such guidelines commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these guidelines, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the guidelines on the incentives for any potential registrant to undertake the development of the required data. Guidelines and modifications thereof having general applicability shall be published in the Federal Register. The Administrator shall provide for public comment for Agency guidance in development of such guidelines or modifications. Within thirty days after the Administrator registers a pesticide product under this Act the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the decision. The data shall not be made available in any manner inconsistent with the provisions of section 10 of this Act.";

(3) by amending subsection (c)(2)(B) to read as follows:

"(B) ADDITIONAL DATA TO SUPPORT EXISTING REGISTRATION.—

"(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide product (or a category of products) containing a particular active ingredient, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person. The notice shall specify the data required, the date by which the data shall be submitted, and the procedure for obtaining rulings by the Administrator on questions concerning the applicability of the notice to various registrants or concerning the nature of the studies to be conducted and of the data required to be submitted.

"(ii) Each registrant of such a pesticide product to whom the notice is applicable shall provide evidence within one hundred and eighty days after receipt of the notification specified in clause (i) of this subparagraph that it is taking the appropriate steps prescribed by the Administrator to secure the required data. If more than one registrant is subject to the notice, such steps shall include entering into a joint data development arrangement, unless the registrants subject to the notice unanimously agree otherwise. The joint data developers shall furnish to the Administrator the name, address, and telephone number of the person to whom inquiries concerning the arrangement should be addressed. As an initial cost of participation the joint data developers shall divide equally 25 per centum of the estimated total cost of producing the required data or each shall pay $100,000, whichever is less. The balance of the cost of producing the data shall be paid by the joint data developers as needed, and shall be shared by each joint data developer on the basis of its United States market participation for the pesticide being tested, based on total pounds of active ingredient equivalent sold or used annually. Each joint data developer's market participation shall be adjusted during the period of the data development so that the most recent sales figures are used to compute each member's market share for the purpose of determining its share of the remaining cost of producing the required data. Each of the joint data developers shall submit adequate evidence of its annual market participation to an independent auditor for each of the years during the period of the joint data development. Such independent auditor shall be chosen by the joint data developers. The auditor's decisions and determinations shall be final and binding on each of the joint data developers. If further data are required by the Administrator under this paragraph, either before or after the additional data that were originally requested have been submitted, the same formula and procedure specified in this paragraph shall apply as if the subsequent request were the initial request for data. Any registrant who shares in the cost of producing the data shall be entitled to receive a copy of the data, and to examine and rely upon such data in support of maintenance of such registration.

"(iii) Notwithstanding any other provision of this Act, if a registrant who is subject to the notice from the Administrator, within the one hundred and eighty-day period prescribed in clause (ii) of this subparagraph, fails to enter into a joint data development arrangement under that clause, fails to take appropriate steps to secure and submit the required data, or fails to comply with the terms of a joint data development arrangement, the Administrator shall issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data are required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice, or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basic for the notice of intent to suspend. If requested, a hearing shall be conducted under section 6(d) of this Act. The only matters for resolution at that hearing shall be whether the Administrator had a valid and reasonable basis for requiring the additional data, whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide product for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is requested, the hearing shall be held and a decision shall be made within seventy-five days after receipt of such request, and the decision shall be final. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

"(iv) Subject to the provisions of clause (vi) of this subparagraph, data submitted under this subparagraph (before or after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982) shall not be considered by the Administrator to support any application for registration, amended registration, reregistration or experimental use permit on behalf of any person other than the joint data developers for a period of fifteen years after the data are submitted, unless any such person has reimbursed the joint data developers by paying a share of the real costs of producing the data in proportion to the number of persons sharing in such costs. Upon payment, such person shall be considered to be an original participant and shall share in all rights and be bound by all obligations entered into by the original data developers. Such reimbursement shall be made to the original participants based on the percentage of the overall monetary participation in the joint data development arrangement.

"(v) The provisions of this clause shall apply to health and safety data submitted voluntarily by a registrant or applicant at any time after September 30, 1978, to replace data which such person deems scientifically insufficient under generally accepted good laboratory practices or test standards. In order to obtain the rights provided by this clause and clause (iv) of this subparagraph with respect to such data, a registrant or applicant undertaking such a replacement study shall notify the Administrator that the replacement study is being performed or has been performed. The Administrator shall publish any such notification in the Federal Register promptly after its receipt, and shall state therein whether the validity of the study is under review and any determinations as to its validity which have been made. Each person who, as of the date of publication, is a registrant or an applicant for registration of any product containing the active ingredient which is the subject of the study shall have the opportunity to participate in a joint data development arrangement as provided in clause (ii) of this subparagraph. If a registrant or applicant of record as of the date of publication of the notice informs the person undertaking the study, within ninety days of the date of publication, of the registrant or applicant's decision to voluntarily participate, the registrant or applicant shall have the rights and duties of a joint data developer as described in clauses (ii), (iii), and (iv) of this subparagraph.

"(vi) With respect to any study which has been or is being performed in response to a request for additional data issued under this subparagraph between September 30, 1978, and the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, any person who on such date of enactment is the registrant of a product of the type to which that request applies but who is not already a party to an agreement to share in the cost of performing that study shall be entitled to enter into a joint data development arrangement with any person or group which is performing or has performed that study, under which arrangement such person shall have the rights and duties of a joint data developer as follows: in the case where a study is being performed by two or more persons under a joint data development agreement, a registrant who wishes to avail himself of the rights provided by this clause shall be bound by the terms of such agreement; and in all other cases, a registrant who wishes to avail himself of the rights provided by this clause shall share in the cost of producing the data as provided in clause (iv) of this subparagraph and shall be subject to the provisions of clause (iii) of this subparagraph: *Provided*, That any registrant who wishes to be availed of the rights provided by this clause shall, not later than one hundred and twenty days after date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, submit an irrevocable offer to enter into such an arrangement to the person or group which is performing or has performed the study.";

(4) by amending subsection (c)(2)(D) to read as follows:

"(D) EXEMPTION.—No applicant for registration, reregistration or amended registration of a pesticide product who proposes to purchase a registered pesticide product from another producer in order to formulate such purchased pesticide product into an end-use product shall be—

"(i) required to submit or cite data pertaining to the safety of such registered pesticide product or offer to pay compensation otherwise required by paragraph (1)(D) of this subsection and subsection (h) for the use of any such data: *Provided,* That—

"(I) this exemption shall be applicable with respect to data that concern the safety of a new use and that are entitled to exclusive-use protection under subsection (h)(2)(A) of this section, only as long as the person who submitted such data has given written permission to any applicant and all conditions of such permission remain satisfied;

"(II) if at any time after registration, amended registration, or reregistration the Administrator finds that the registrant ceased using a purchased registered pesticide product as the source of the active ingredient in formulating the end-use product, this exemption shall no longer apply;

"(III) if at any time this exemption becomes inapplicable due to the provisions of clause (i)(I) or (i)(II) of this subparagraph, and the registrant fails to agree to supply the data required for registration as set forth in subsection (h)(2) of this section, the Administrator shall issue an order suspending the registration and a notice providing the registrant an opportunity for a hearing on whether the suspension should be revoked because the registrant is entitled to the exemption. If requested, a hearing shall be conducted as provided under section 6(d) of this Act, except that the only issue to be decided shall be whether the registrant is entitled to an exemption under this subparagraph. The provisions of section 6(d) of this Act regarding referral of matters to a Committee of the National Academy of Sciences shall not apply to such a hearing; and

"(IV) the Administrator may require the submission of data pertaining solely to the safety of a changed use pattern proposed for the end-use product if such data have not already been submitted to the Administrator; or

"(ii) subject to a notice issued under paragraph (2)(B) of this subsection for additional data concerning the safety of the purchased product or of the active ingredients thereof.

Nothing contained in subsection (h)(2) of this section shall limit the provisions of this exemption.";

(5) in subsection (c)(3) by inserting "or (7) of this subsection" immediately after "with paragraph (5)", and by inserting "of this subsection" immediately after "with paragraph (6)";

(6) in subsection (c)(8) by inserting the designation (A) immediately before "Notwithstanding any other provision of this Act", and adding new subparagraphs at the end thereof as follows:

"(B) At least ninety days prior to initiating a public interim administrative review process, the Administrator shall notify all affected registrants of the risks upon which the proposed review will be based. In finally determining whether to initiate a public interim review, the Administrator shall consider any correcting or clarifying data or other information submitted by a registrant, or other interested person, including data on human or environmental exposure. If after giving notice to registrants under this subparagraph, the Administrator determines that it is not necessary to initiate a public interim review, then the Administrator shall make the reasons therefor available to the public.

"(C) The Administrator shall not by regulation or otherwise utilize a public interim administrative review process to abridge entitlement to a public hearing in accordance with section 6 of this Act.

"(D) A decision by the Administrator not to cancel or suspend the registration of a pesticide product or any use thereof or not to restrict the classification of a pesticide, following an interim administrative review, shall be subject to judicial review under section 16(a) of this Act, and any person who has participated in such interim administrative review shall have standing in any such judicial review proceeding.";

(7) by amending subsection (d)(1)(C)(ii) to read as follows:

"(ii) if the Administrator classifies a pesticide, or one or more uses of a pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such restrictions, including but not limited to geographic, hydrogeologic, soil-specific or seasonal restrictions, as the Administrator may provide by regulation: *Provided,* That any such regulation that contains restrictions that apply to the applicator shall require an appropriate notice of such restrictions on the label. Any such regulation shall be reviewable in the appropriate court of appeals upon petition filed within sixty days after the effective date of the regulation by a person adversely affected by the regulation.";

(8) by adding at the end of subsection (g) the following: "The Administrator shall furnish registrants reasonable notice, not less than ninety days, of when they must apply for reregistration of their products. If an application for reregistration of a product is not received by the date specified in such notice, the Administrator shall issue an order canceling the product's registration. The Administrator may include in the order such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of the product. An order issued under this subsection shall be subject to judicial review under section 16(a) of this Act. A cancellation of a product's

registration under this subsection shall not affect the right of a person whose registration was canceled to apply for a new registration of that product or a similar product in the future."; and

(9) by adding a new subsection at the end thereof as follows:

"(h) USE OF DATA.—

"(1) DEFINITIONS.—For the purpose of this subsection:

"(A) The term 'pesticide product that contains a new active ingredient' means a pesticide product that is first registered after September 30, 1978, and that contains an active ingredient which as of the date of that product's first registration, has not been listed as an active ingredient in the ingredient statement of any other registered pesticide product.

"(B) The term 'new use' means, with respect to any active ingredient, a use:

"(i) that is or was approved for registration for the first time after September 30, 1978;

"(ii) that was not part of the original registration for such active ingredient; and "(iii) for which, because of differences between the use and other previously-registered uses of products containing that active ingredient, the Administrator requires or required the submission of data pertaining to the use as a prerequisite to or condition of registering any product for the use.

"(C) The term 'new use data' means data concerning a product's active ingredient(s) submitted to support an application to amend a registration of a pesticide product by adding a new use, or to register a pesticide product with a new use, conditionally or unconditionally. The term shall not include data that pertain to a different, previously registered use that is not a new use.

"(D) The term 'old-ingredient data' means data submitted to the Administrator that concern the safety or effects of any product registered under this Act before the data were submitted, or that concern the safety or effects of any active ingredient of any such product, but shall not include data submitted to fulfill the conditions of a conditional registration under subsection (c)(7)(C) of this section.

"(E) The term 'data concerning a product's active ingredient' includes data from a test performed using the technical or purer grade of the active ingredient, and data from a test performed using an end-use product or other test substance that is intended to provide information concerning the safety or effects of the active ingredient.

"(F) The term 'data required for registration' means the minimum kinds and number of studies which the Administrator would require in order to approve an application for unconditional registration under subsection (c)(5) of this section of a product with composition and labeling identical or substantially similar to that of the applicant's product, including data sufficient to satisfy guidelines issued under subsection (c)(2)(A) of this section: *Provided,* That to the extent that any such data have not been generated by any applicant or registrant or have been determined by the Administrator to be invalid, the provisions of subsection (c)(7) of this section shall apply: *Provided further,* That for purposes of a manufacturing-use registration, the data required for registration shall include not only the data required solely for registration of the manufacturing-use product, but also all data concerning the active ingredient of the product required for registration of all registered end-use products which the manufacturing-use product can be used to formulate, except to the extent that the label of the manufacturing-use product prohibits its use for the formulation of such an end-use product.

"(2) DATA REQUIREMENTS.—An applicant shall supply the data required for registration as set forth in this paragraph. The applicant shall submit data or cite data previously submitted to the Administrator, or use any combination of those two methods, except to the extent that the applicant is precluded from relying on data by the following provisions:

"(A)(i) The following data shall not, without the written permission of the original data submitter, be relied on by any other applicant to support any application for any registration (conditional or unconditional), amended registration, or reregistration, or experimental use permit during a period commencing with the date the data are originally submitted and ending fifteen years after the date the Administrator approves the original data submitter's application for registration or amended registration:

"(I) data (other than old-ingredient data) submitted to support the application for the original conditional or unconditional registration of a product that is, or if registered will be, a pesticide product that contains a new active ingredient and data subsequently submitted to fulfill the conditions of such a conditional registration under subsection (c)(7)(C) of this section; and

"(II) data (other than old-ingredient data) submitted after the effective date of this provision to support an application for an experimental use permit for a pesticide product containing a new active ingredient.

"(ii) New use data pertaining to an active ingredient which was not an active ingredient of any product registered ~~on or before September 30, 1978~~, shall not, without the written permission of the original data submitter, be relied on by any other applicant to support any application for registration (conditional or unconditional), amended registration, reregistration, or experimental use permit, for a period commencing with the submission of the data and ending fifteen years after the date of the first registration for any new use of any product containing that active ingredient.

"(iii) New use data pertaining to an active ingredient which was not an active ingredient of any product registered before January 1, 1970, but which was an active ingredient of one or more products registered on or before September 30, 1978, shall not, without the written permission of the original data submitter, be relied on by any other applicant to support any application for registration (conditional or unconditional), amended registration, reregistration, or experimental use permit, for a period commencing with the submission of the data and ending on September 30, 1993.

"(B) During the period in which data of an original data submitter are entitled to exclusive use protection under subparagraph (A) of this paragraph, any subsequent applicant also may obtain a registration for a product having the same new active ingredient or new use, or may obtain a permit for the same experimental use, by independently submitting to the Administrator the data required for registration or for the permit and by satisfying the pertinent requirements of section 3(c)(5), 3(c)(7), or 5 of this Act. Data of the type described by subparagraphs (A)(i), (ii), and (iii) of this paragraph submitted by such subsequent applicant shall be entitled to the same exclusive use protection as described in subparagraph (A) of this paragraph, but only for the duration of the period of exclusive use remaining for data submitted by such original data submitter, and can be relied upon by others only with the written permission of the subsequent applicant.

"(C) Data concerning a product's active ingredients submitted pursuant to subsection (c)(2)(B) of this section may be relied on by an applicant only in accordance with the provisions of that subsection.

"(D) Data concerning a product's active ingredients not described by subparagraph (A), (B), or (C) of this paragraph and submitted by an applicant or registrant after December 31, 1969, but on or before September 30, 1978, to support an application for registration, experimental use permit, amended registration, or reregistration or to support or maintain in effect an existing registration, may not, during the fifteen-year period following the date the data were originally submitted, be relied on in support of an application by any other person (hereinafter referred to in this subparagraph as the 'applicant') without the written permission of the original data submitter, unless the applicant has made an offer to compensate the original data submitter and submitted to the Administrator evidence of delivery of the offer to the original data submitter. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor agreed on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide product in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide product. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

"(E) Except as provided in subparagraphs (A) through (D) of this paragraph, an applicant may rely on any item of data without obtaining the permission of the original data submitter and without offering to compensate the original data submitter for the use of such item of data. Notwithstanding any other provision of this section, an original submitter of an item of data shall be entitled to rely on the provisions of subsection (h)(2) (A), (B), or (D) of this section with respect to that item of data only if the original submitter (or its predecessor in interest) generated the data, paid for the generation of the data, or purchased the rights in the data afforded under this subsection.

"(F) Notwithstanding any other provision of this Act, no provision of subsection (h) of this section shall abridge the right of an applicant or registrant to obtain a registration, reregistration, amended registration, or experimental use permit (i) solely on the basis of data independently developed and submitted by the applicant or registrant itself, (ii) except as provided in subparagraphs (A) through (D) of this paragraph, on the basis of previously submitted data cited or submitted by an applicant or registrant, or (iii) any combination of the foregoing; and the Administrator shall not in any way abridge such right.

"(G) The Administrator may approve an application only upon a determination that the application is in compliance with subsection (h) of this section. If an applicant has submitted or cited data which are required for registration in a manner consistent with subsection (h), the Administrator may then review any other data in deciding whether approval of such application would cause (or would significantly increase the risk of) unreasonable adverse effects on the environment.

"(H) An applicant for registration of an end-use product shall provide to the Administrator the identity of the source of the active ingredient in the end-use product. The applicant shall certify to the Administrator in its application that the uses for which registration is sought are not prohibited by the label of any manufacturing-use product that the applicant will use as the source of such active ingredient. During the period that the applicant's registration is in effect, the applicant shall report to the Administrator any change in the source of such active ingredient.

"(I) An applicant for registration of a product whose active ingredients and intended uses are identical or substantially similar to those of one or more already registered products need not submit or cite data concerning any of the product's active ingredients unless data of the same type for such ingredients appear on the indexes prepared in accordance with subparagraph (J) of this paragraph.

"(J) The Administrator shall compile, for each active ingredient affected, an index comprised of each item of data described by subparagraphs (A), (B), (C), and (D) of this paragraph. For each such item of data, the list shall set forth the date the item of data was originally submitted, the identity of the original submitter, a brief description of the kind of study that yielded the data, and the subparagraph of subsection (h)(2) that describes the data. The Administrator shall make the first such set of indexes available for release to the public not later than one year after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982. An item of data that was originally submitted to the Administrator on or before the date of enactment of this subparagraph may be included on any such index only if, not later than one hundred and eighty days after such date of enactment, the Administrator has received from the original submitter of that item of data a written statement setting forth the date the item of data was originally submitted, a brief description of the kind of study that yielded the data, the subparagraph in this paragraph that describes the data, the Environmental Protection Agency data accession number (if known), and the reasons why the item of data is entitled to be included in the index. The Administrator shall update the indexes, at least semiannually by adding any item of data described by subparagraph (A), (B), or (C) of this paragraph and submitted after the effective date of these amendments, and by deleting items of data which no longer are described by subparagraph (A), (B), (C), or (D) or which the Administrator finds were incorrectly included on the indexes. The updated indexes shall be made available to the public. An index shall be deemed to include any item of data which is entitled to be in the index but which was received by the Administrator too recently to have been included in the most recent update of the index. A decision by the Administrator to include an item of data in such an index, or to exclude it, shall be subject to judicial review under section 16(a) of this Act.

"(K) At the request of an applicant for registration of a product containing a particular active ingredient, the Administrator shall require the original submitter of any items of data which concern that active ingredient, but which are not included or deemed to be included on any index compiled under subparagraph (J) of this paragraph, to furnish a report, within a reasonable period of time to be specified by the Administrator, which briefly describes the type of study that yielded each such item of data, states the date each such item of data was originally submitted, and states any accession numbers or other identifying information (if known) used by the Agency to catalog the items of data.

"(L) Each application for registration of a new product, for reregistration, for an experimental use permit, or for amendment of an existing registration to add a use shall include a list of the applicable data requirements, a list of the data the applicant is submitting or citing to satisfy each such requirement, and a certification that the applicant is not precluded by subparagraph (A), (B), (C), or (D) of this paragraph from relying on any of the data listed with the application. After the Administrator has approved an application, the lists and certification shall be available to the public. Any data submitter who claims that such an applicant has incorrectly listed the applicable data requirements, has not submitted or cited data sufficient to satisfy those requirements, has not submitted a required authorization from a data submitter or otherwise has failed to comply with subsection (h) of this section, and who claims, in that person's capacity as the original submitter of data included on an index described by subparagraph (J) of this paragraph, to have been adversely affected by the approval of the application may petition the Administrator to hold a hearing to determine whether the registration should be canceled. Such petition shall be in writing and shall contain a detailed statement of reasons why the registration should be canceled. Upon receipt of the petition, the Administrator shall afford the registrant a reasonable period of time, not to exceed sixty days, to respond to the petitioner's allegations. The Administrator shall then issue a written decision within thirty days, specifying what action to take on the petition.

"(i) If the Administrator finds that the petition and any response show that there is no reasonable possibility that a hearing would lead to cancellation of the registration for the reasons set forth in the petition, the Administrator shall deny the petition. Any such denial shall be subject to judicial review under section 16(a) of this Act. The reviewing court shall not allow discovery proceedings nor receive testimony or evidence, and shall base its review solely on the petition, the registrant's response, the Administrator's decision, and the pleadings and briefs filed with the court. If the court finds that the Administrator's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, the court shall remand the matter to the Administrator for purposes of holding a hearing under this subparagraph. If the court does not so find, the case shall be dismissed.

"(ii) If the Administrator finds that the petition and any response indicate that there is a reasonable possibility that a hearing may lead to cancellation of the registration for the reasons set forth in the petition, or if the Administrator is ordered by a court to hold a hearing, the Administrator shall issue a notice of intent to hold a hearing to determine whether the product's registration should be canceled, which notice shall be furnished by certified mail to the registrant and the petitioner. The hearing shall be held in the manner provided by section 6(d) of this Act: *Provided*, That the provisions of that section regarding referral of matters to a Committee of the National Academy of Sciences shall not apply to such a hearing: *And provided further*, That the petitioner shall have the burden of proving that the registration should be canceled. The Administrator's order following such a hearing shall be issued within ninety days from the date of the notice of intent to hold a hearing. An order following such a hearing that cancels the registration of a product shall take effect immediately upon issuance. Review of the Administrator's order following such a hearing shall be governed by section 16(b) of this Act. The provisions of this subparagraph and of subparagraph (M) of this paragraph shall constitute the sole and exclusive means of review, at the behest of any person other than the Administrator, of the extent to which an application for registration complies with subsection (h) of this section, notwithstanding the other provisions of this Act, chapters 5 and 7 of title 5 of the United States Code, or any other statute.

"(M) For the purpose of enforcing exclusive rights to data submitted to obtain new use registration pursuant to paragraph (2)(A) (ii) and (iii) of this subsection, each applicant for registration of a product with uses previously registered by another registrant shall be required to certify that the applicant has reviewed the indexes prepared pursuant to paragraph (2)(J) and any provisional indexes prepared pursuant to paragraph (5) of this subsection, and further that the applicant is not relying on data submitted by another person, without the written permission of such person, that the indexes show to be unavailable for use because of exclusivity rights provided under paragraph (2)(A) (ii) and (iii) of this subsection. Such certification shall not be required from an applicant who is exempt from submitting or citing the data required for approval of the registration under subsection (c)(2)(D) of this section, and the procedures described in this paragraph shall not apply to such person. Upon receiving the required certification, the Administrator may process an application without determining the validity of any statement contained in such certification. Not later than thirty days before approving the application, the Administrator shall make available to the public the name of the applicant submitting such certification, the active ingredients in the applicant's product, and the uses for which registration is sought. Before petitioning the Administrator to hold a hearing to determine whether such registration should be denied (or if it has been approved, canceled), a person who claims that the applicant has failed to comply with subsection (h) of this section and that the person would be adversely affected by such approval in that person's capacity as the original submitter of data included on such index shall notify the applicant in writing of such position. Within thirty days after receiving this notice, the applicant shall deliver a response in writing to the data submitter. The Administrator may withhold action on the application until ten days after the data submitter receives the applicant's response. After receiving the response, the data submitter may petition the Administrator to hold a hearing to determine whether to approve the applicant's registration, or to cancel such registration if it has been approved. The Administrator may withhold approval of the registration upon finding that the petitioner is likely to prevail in the dispute. If the Administrator at any time finds that the petitioner acted without good cause in prosecuting the dispute or that the applicant acted without good cause in refusing to withdraw an application that relies on the petitioner's data in violation of this section, the Administrator may award attorney's fees or costs of prosecuting or defending the dispute against the person acting without good cause, and may award damages suffered by the party that acted in good faith. In all other respects, the petition shall be processed in accordance with the procedures specified in paragraph (2)(L) of this subsection, and the Administrator's decision shall be subject to review as provided in paragraph (2)(L).

"(3) Except as provided in paragraphs (4) and (5) of this subsection, the provisions of paragraph (2) of this subsection shall not become effective with respect to the approval of applications under this Act until eighteen months after enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982.

"(4) With respect to any application for registration of a pesticide product that contains a new active ingredient (and contains no other active ingredient), or for registration of any other product containing the same active ingredient, that could be registered under this Act but for the provisions of sections 162.9–3 and 162.9–4 of title 40, Code of Federal Regulations, in effect on the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, the following paragraphs shall become effective immediately upon enactment of such amendments:

"(A) Paragraph (2)(F) of this subsection, except for clauses (ii) and (iii) thereof; and

"(B) Paragraph (2)(G) of this subsection.

"(5) With respect to any application to amend a registration of any pesticide product by adding a new use, or to register a product with a new use, paragraphs (2)(A), (2)(L), and (2)(M) of this subsection shall become effective immediately upon the submission by the applicant of a provisional index of the applicant's data submitted to support the new use in the form prescribed by paragraph (2)(I) of this subsection, and the publication of such provisional index in the Federal Register. The Administrator may charge the applicant a fee to cover the cost of publishing the index, which fee shall be placed in a revolving fund to be used for the payment of publishing charges.

"(6) Offers to pay compensation under subsection (c)(1)(D) of this section made before enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982 shall be governed by the law in effect at the time the offer was made.

"(7) Except as provided in paragraph (3) of this subsection, with respect to applications approved before expiration of the eighteen-month period after enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, an applicant shall supply the data required under this paragraph. An applicant shall file a statement that includes, except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

"(A) with respect to pesticides containing active ingredients that are initially registered under this Act after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of fifteen years following the date the Administrator first registers the pesticide: *Provided,* That such permission shall not be required in the case of old-ingredient data;

"(B) except as otherwise provided in subparagraph (A) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the 'applicant') within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this paragraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this paragraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this paragraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take actions and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation;

"(C) after expiration of the period (if any) of exclusive use and any period (if any) for which compensation is required for the use of an item of data under paragraphs (A) and (B) of this subsection, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.".

CANCELLATION AND CHANGE IN CLASSIFICATION

SEC. 4. Section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act is amended—

(1) by amending clauses (1) and (2) of the first sentence to read as follows:

"(1) to cancel or phase out its registration, or to change its classification, together with the reasons (including the factual basis) for such action, or

"(2) to hold a hearing to determine whether or not its registration should be canceled or phased out, or its classification changed.";

(2) by striking out the third sentence and inserting in lieu thereof the following: "In determining whether to issue any such notice, the Administrator shall include among the factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on agricultural producers, and on the agricultural economy. The determination of such impacts shall be based on biologic and economic assessments, including but not limited to any prepared by the Department of Agriculture."; and

(3) by striking out the last sentence and inserting in lieu thereof the following: "In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on agricultural producers and on the agricultural economy, and the Administrator shall publish in the Federal Register a notice of availability of an analysis of such impacts. In preparing the final analysis of such impacts, the Administrator shall fully consider all comments on the proposal, including those provided by the Secretary of Agriculture.".

PROTECTION OF TRADE SECRETS AND OTHER INFORMATION

SEC. 5. Section 10 of the Federal Insecticide, Fungicide and Rodenticide Act is amended—

(1) by amending subsection (a) to read as follows:

"(a) IN GENERAL.—

"(1) At the time of submitting information required by this Act, the data submitter shall clearly mark portions thereof believed to fall within the following categories: trade secrets; privileged or confidential commercial or financial information; and data described by subsection (d)(2)(B) of this section. The data submitter also shall explain why each marked portion falls within the designated category and the extent to which it is protected from disclosure or transfer under this section, and shall submit such marked materials separately from the other material required under this Act. Any data (or portions thereof) not so marked submitted more than sixty days after enactment of the Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1982 shall be available to the public without regard to any protections provided in this Act for information that falls within such categories.

"(2) Before disclosing or making available any information under this section that was submitted prior to the effective date of the interim final regulations promulgated pursuant to this subsection (other than information which has already been made available to a member of the public or which the data submitter has previously indicated do not fall within the categories described in paragraph (1) of this subsection), the Administrator shall afford the data submitter a reasonable period of time, not to exceed sixty days from the date of receipt by the data submitter of a request by the

Administrator, to identify any portions of the information that the data submitter claims to fall within the categories described in paragraph (1) of this section and to substantiate such claims. If no claim is made within the period afforded, or if the Administrator finds the claim to be without merit, the information shall be made available in accordance with this section.

"(3) A data submitter may file with the Administrator a designation of a representative authorized to receive communications regarding matters arising under this section, in which case all time periods subsequently requiring or permitting action by the data submitter under this section shall begin to run from the date of actual receipt of any notice by such representative.";

(2) by amending subsection (c) to read as follows:

"(c) DISPUTES.—If the Administrator proposes to make the initial public disclosure or transfer of any item of data which the data submitter has claimed to be protected from disclosure or transfer by this section, but which the Administrator determines is not so protected, the Administrator shall notify the data submitter, in writing, by certified mail. The Administrator shall not thereafter make the item of data available to the public until thirty days after receipt of the notice by the data submitter. During this period, the data submitter may institute an action in an appropriate district court for a declaratory judgment as to whether such information is protected from the proposed disclosure or transfer. The procedures prescribed by this subsection shall apply only to the first time a given item of data is disclosed to the public. This subsection shall not apply to any proposed disclosure under subsection (d)(4) of this section.";

(3) by amending subsection (d)(1) to read as follows:

"(d) LIMITATIONS.—

"(1) Notwithstanding any provision of section 552, of title 5, United States Code or any other law, to the contrary, but subject to the provisions of this section, all information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public as provided in paragraphs (2) and (3) of this subsection: *Provided*, That the use of such data for any registration purpose shall be governed by section 3 of this Act: *Provided further*, That this paragraph does not authorize the disclosure of any information that—

"(A) discloses manufacturing or quality control processes,

"(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

"(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

In exercising its authority under section 24(a) of this Act, a State may, however, obtain information described by clauses (B) and (C) of this paragraph, but shall not disclose any such information except to the extent such information has been disclosed by the Administrator under this section.";

(4) by redesignating subsections (d)(2) and (d)(3) as subsections (d)(3) and (d)(4), respectively, and strik-

ing out in subsection (d)(4), as redesignated, "paragraph (2)" wherever it appears and inserting in lieu thereof "paragraph (3)";

(5) by adding a new subsection (d)(2) to read as follows:

"(2)(A) REGULATIONS.—The Administrator shall expeditiously promulgate regulations to implement subsections (d) and (f) of this section. The regulations shall establish procedures pursuant to which information that may be disclosed under subsections (d)(1) and (f) of this section shall be made available to the public. The regulations shall—

"(i) permit all persons not excluded by subsection (f) of this section, including, but not limited to, employees of the United States, agencies of State governments, and authorized scientific personnel representing an employee of a pesticide producer or registrant or the employee's trade union, to obtain copies of data, subject to specified conditions governing further copying or transfer of the data;

"(ii) prescribe the conditions under which the data are to be maintained while they are being used;

"(iii) prescribe procedures permitting publication of any information contained in the data regarding the health, safety, or environmental effects of a product (except as provided in paragraph (2)(B) of this subsection), including but not limited to protocols and results of environmental and toxicological studies; and

"(iv) prescribe procedures for submission of such information in litigation and administrative proceedings under adequate protective orders. Such restrictions, conditions and procedures shall apply to the use and disclosure of data only to the extent necessary to prevent use of the data by persons other than the data owner to obtain or maintain registrations (or other governmentally required approvals) of pesticide products, and to prevent violations of subsection (f) of this section in order to protect the proprietary rights of data owners against the use of their data by competitors as provided in this Act. Notwithstanding any provision of this Act or of any other law, interim final regulations shall be promulgated and become effective within sixty days after enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, and the provisions of section 25(a) of this Act shall not apply to the promulgation of such interim regulations. At least fifteen days before submitting the interim final regulations for publication in the Federal Register, the Administrator shall furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate. The interim final regulations shall be superseded as soon as possible (allowing time for notice and comment) by final regulations. The provisions of this section and the regulations promulgated thereunder shall apply with respect to all data submitted to the Administrator, whether before or after the enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982.

"(B) INNOVATIVE METHODS AND TECHNOLOGY.—For the purpose of this section, the term 'innovative methods and technology' means innovative methods or technology (including innovative methods of using known technology) that are not otherwise publicly available, that are employed in obtaining product chemistry, environmental chemistry, residue chemistry, and metabolism data, that are substantially different from known methods or technologies, and innovative compositions of matter, and that, if disclosed, could provide a significant advantage to competitors of the submitter of the data. In no event shall an item of data be considered to be an innovative method or technology for longer than five years after the date of submission to the Administrator or the date of first registration in the case of a new active ingredient. The regulations promulgated under paragraph (2)(A) of this subsection shall establish separate procedures for making data concerning innovative methods and technology available to the public. The innovative methods and technology shall be made available to scientists acting on behalf of Federal or State agencies, independent scientists working in the field to which the data pertain (and otherwise qualified to receive data under subsection (f) of this section), and scientists and staff representatives acting on behalf of nonprofit health, environmental or labor organizations, seeking access to the data to conduct an independent peer review or replicate the study, but shall not otherwise be made available to the general public. The regulations shall establish procedures by which such scientists and representatives may communicate with each other and with the Administrator, and in judicial or administrative proceedings, concerning the innovative methods and technology without disclosing them to the public. Upon request by any such scientist or representative, in writing, by registered mail, the submitter of data concerning the innovative methods and technology shall provide to such requester, within fifteen days after receipt of the written request, a summary of the data for disclosure to the general public. If such summary is not provided within the specified time period, the data shall no longer be considered to concern an innovative method or technology under this paragraph. Any person who is given access to data concerning innovative methods or technology may, after such review or replication has been conducted, request the Scientific Advisory Panel to review such data. The Panel shall be subject to the same conditions regarding disclosure of such data as any other data recipient under this section. If the Panel, after notifying the data submitter and providing interested parties an opportunity to comment, finds that the data does not concern an innovative method or technology or is invalid, or that disclosure is necessary and in the public interest because of concerns as to protection of health, safety, or the environment, it may make recommendations to the Administrator, including a recommendation that such data be made available under paragraph (2)(A) of this subsection. If the Administrator concurs in the recommendation of the Panel, the Administrator may make the data available to the public. The Administrator's decision shall be subject to judicial review under section 16(a) of this Act.";

(6) by amending subsections (f) and (g) to read as follows:

"(f) DISCLOSURE TO PESTICIDE PRODUCERS AND FOREIGN NATIONALS.—Except as otherwise provided in this section, the Administrator shall not, without the consent of the data submitter, knowingly allow access to information, submitted by an applicant or registrant under this Act, to any person engaged in, or who intends to engage in, the production or registration of pesticides (pesticide producer), or to any employee or agent of a pesticide producer, or any other person who intends to disclose such data to a pesticide producer, or to any foreign national not residing in the United States or who will remove the data from the United States. Notwithstanding any other provision of this section, during administrative adjudicatory hearings or court litigation a party who is a pesticide producer or registrant may, pursuant to an appropriate protective order issued by the court or presiding administrative official, examine and obtain a copy of data submitted by another person (other than data described by subsection (d)(1) (A) through (C) or subsection (d)(3) of this section), if the party's access to the data is found to be necessary in order to allow the party to participate fully in the hearing or litigation.

"(g) INTERNATIONAL AGREEMENTS.—Notwithstanding any other provision of law—

"(1) The Administrator shall not make available for public inspection any document or information concerning pesticides if—

"(A) the Administrator obtained the document or information from the government of another country (or from an international organization of countries);

"(B) the government or international organization required the Administrator to agree not to disclose the document or information to the public as a condition of furnishing it to the Administrator;

"(C) the Administrator could not otherwise obtain the document or information; and

"(D) the government or international organization continues to demand that the document or information not be made available for public inspection.

"(2) The Administrator may disclose information obtained under this Act to the government of another country or its agents (or to an international organization of countries) only under the following conditions. The information that may be so disclosed shall include all information that may be publicly disclosed under subsection (d)(1) of this section but shall not include any information described in subsection (d)(1) (A), (B), or (C), or (d)(3) of this section. The Administrator shall not make such disclosures unless an agreement has been entered into with the other country which furnishes assurances acceptable to the Administrator that the government of that country—

"(A) will not further disclose the information without the consent of either the Administrator or the submitter of the information; and

"(B) will not allow the information to be used directly or indirectly to support any application for, or decision to grant, a license, permit, or other action which allows the production, sale, or distribution of a pesticide under any country's laws.

The Administrator shall provide notice to affected persons and an opportunity for comment prior to entering into any such agreement with the government of another country. The Administrator shall provide notice to the data submitter of the proposed transfer of data to a foreign government under any such agreement. The Administrator shall not consent to any public disclosure of information by a foreign government under subparagraph (A) of this paragraph that would have the effect of permitting the disclosure of information that is otherwise prohibited under this Act, or permitting disclosure under conditions that are less restrictive than those permitted by this section and any regulations promulgated thereunder.";

(7) by adding two new subsections as follows:

"(h) Civil Action.—Any data submitter under this Act, who is or may be adversely affected by a violation (or threatened violation) of this section by any person (other than a Federal or State official) who is acting willfully in furtherance of a commercial purpose, may bring an action in an appropriate United States district court against such person to prevent and restrain such violation or obtain damages, or both. The court shall award treble the actual damages shown, and shall award punitive damages for a gross violation. A data submitter also may bring an action in an appropriate United States district court against the Administrator or against any agency official specifically to enforce, or restrain violations of, this section.

"(i) UNLAWFUL ACTS.—It shall be unlawful (A) for any person who has obtained information from the Administrator under this section to disclose or transfer the information in a manner prohibited by this section or by regulations implementing this section; (B) for any person to solicit or abet any disclosure or transfer of information that is unlawful under clause (A) of this subsection; or (C) for any person to make commercial use of information that such person received under this section or through a disclosure or transfer that such person knew or should have known to be unlawful under clause (A) of this subsection.".

UNLAWFUL ACTS

SEC. 6. Section 12(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act is amended—

(1) by striking out "or" at the end of clause (O);

(2) by striking out the period at the end of clause (P) and inserting in lieu thereof "; or"; and

(3) by adding a new subparagraph at the end thereof as follows:

"(Q) to discharge from employment or otherwise adversely affect the employment status (including the compensation, terms, conditions, or privileges of employment) of any employee because that person (or any person acting pursuant to a request of the employee) has exercised rights under this Act, filed complaints concerning alleged violations of this Act, testified or is about to testify in any such proceeding (including proceedings concerning alleged violations of this Act), or assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.".

PENALTIES

SEC. 7. Section 14 of the Federal Insecticide, Fungicide, and Rodenticide Act is amended—

(1) by redesignating paragraphs (3), (4), and (5) in subsection (a) as paragraphs (4), (5), and (6), respectively;

(2) by adding a new paragraph (3) as follows:

"(3) DISCLOSURE OF DATA.—Any person granted access to data pursuant to subsection (d) of section 10 of this Act who violates the provisions of that subsection or the regulations promulgated thereunder, or the provisions of section 10(i), or who knowingly accepts, obtains or uses data prohibited from disclosure under section 10(d), 10(f), or 10(g), or under regulations promulgated under section 10(d)(2), may be assessed a civil penalty by the Administrator of not more than $100,000 for each document or study accepted, obtained or used in violation of section 10, and may be denied further access to any data, temporarily or permanently. All registrations issued to such person and to anyone on whose behalf such person was acting shall be summarily canceled without regard to procedures for cancellation in section 6 of this Act that may otherwise be applicable, except to the extent that the Administrator determines that such action would cause injury to the public health, or undue hardship to agricultural producers or other persons making use of the end-use pesticide product. In the case of any violation referred to in this paragraph that was not perpetrated in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide, the only penalty shall be temporary or permanent denial of further access to data by the violator and such other persons and organizations on whose behalf the violator was acting.";

(3) by amending the redesignated paragraph (5) to read as follows:

"(5) DETERMINATION OF PENALTY.—In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty in light of the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that a violation occurred despite the exercise of due care, or that the violation did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty. In determining the amount of the penalty in the case of a violation as described in paragraph 3 of this subsection, or as described in section 10(i) of the Act, the Administrator shall consider only the gravity of the violation."; and

(4) by amending subsection (b)(3) to read as follows:

"(3) DISCLOSURE OF INFORMATION.—

"(A) Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than $100,000, or imprisoned for not more than three years, or both.

"(B) Any person granted access to data under section 10(d) who in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide knowingly violates the provisions of section 10(d), 10(f), 10(g), or 10(i) of this Act, or knowingly allows such data to be made available in violation of the provisions of section 10 of this Act to any person engaged in the production or registration of pesticide products or any employee or agent thereof, shall be fined not more than $100,000 or imprisoned for not more than one year, or both.

"(C) Any officer or employee of the United States or any State, or any former officer or employee of the United States or any State, who, by virtue of such employment or official position has obtained possession of, or has access to material the disclosure of which is prohibited by section 10, and who, knowing that disclosure of such material is prohibited by such section, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than $100,000, or imprisoned for not more than one year, or both. For the purpose of this subparagraph, any contractor with the United States who is furnished information as authorized by section 10(e), or any employee of any such contractor, shall be considered to be an employee of the United States.

"(D) Section 1905 of title 18 of the United States Code shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act. Nothing in this Act shall preempt any civil remedy under State or Federal law for any disclosure prohibited under section 10.".

EXTENSION OF THE SCIENTIFIC ADVISORY PANEL

SEC. 8. Section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act is amended by striking out "September 30, 1981" and inserting in lieu thereof "September 30, 1984".

EXTENSION OF THE AUTHORIZATION FOR APPROPRIATIONS

SEC. 9. Section 31 of the Federal Insecticide, Fungicide, and Rodenticide Act is amended by adding at the end thereof the following new sentence: "There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1982, and ending September 30, 1983, $44,208,000, and for the period beginning October 1, 1983, and ending September 30, 1984, such sums as may be necessary.".

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II

97TH CONGRESS
2D SESSION

S. 2621

To amend the Federal Insecticide, Fungicide, and Rodenticide Act.

IN THE SENATE OF THE UNITED STATES

JUNE 10 (legislative day, JUNE 8), 1982

Mr. HAYAKAWA introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. Section 24 of the Federal Insecticide, Fungicide, and Rodenticide Act is amended by—

(1) amending subsection 24(a) to read as follows:

"(a)(1) A State, but not a political subdivision of a State, may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent that the regulation does not permit any sale or use prohibited by this Act.

"(2) If a State, but not a political subdivision of a State, in regulating the sale or use of a federally registered pesticide or device in the State wishes health and safety data submitted for review in connection with a State registration or approval, the following shall apply:

"(A) With respect to data previously submitted in support of the Federal registration, the State may request the applicant to submit such data to the State for review, and if the applicant does not provide the State such data as is requested, the Administrator shall make the data available to the State, subject to the provisions of section 10. At the option of the State, the data may be obtained from the Administrator under the provisions of section 10 without first making the request to the registrant, but providing the registrant notice thereof. The applicant may provide a letter establishing the applicant's right to cite data previously submitted to the State or to the Agency by another applicant or registrant.

"(B)(i) A State may require submission of additional data with respect to any special local concerns relating to either an increased risk of any unreasonable adverse effect on the environment from the uses of such pesticide or device in the State, or a reduced efficacy of the pesticide or device in the State for the uses for which the application to the State is made: *Provided,* That the State shall give the applicant written notice at the time of the request of the purpose and justification of the requirement. For purposes of this subsection, a special local concern shall arise only when the State obtains significant factual information which reasonably supports the conclusion that the use of any pesticide or device within the State presents a concern relating to either an increased risk of any unreasonable adverse effects on the environment or a reduced efficacy of such pesticide within the State.

"(ii) If the applicant wishes to contest the request for data described in clause (i) of this subparagraph, the applicant may submit the request to the Administrator for review. In reviewing the request, if the Administrator determines that there is a Federal interest, such that the request should be made by the Administrator, the Administrator shall require the applicant to submit the additional data under section 3(c)(2)(B) of this Act. The State's determination of a special local concern pursuant to this section shall be subject to review by the Administrator and shall be subject to judicial review. The Administrator may overrule or modify the State request for additional data if the Administrator determines that the request is arbitrary or capricious, or determines that there exist sources of comparable data that would be available to the State for the purposes of satisfying its request and so notifies the State. The State and the applicant may submit to the Administrator any additional information pertaining to the data request. The Administrator shall publish in the Federal Register the basis for any determination that overrules or modifies the State request. A State may obtain judicial review of a decision by the Administrator to overrule or modify the State's data request. The applicant may seek judicial review of the determination of the State to require the data either before or after the matter has been submitted to the Administrator for review and the Administrator has made a determination: *Provided,* That the Administrator shall not be a party to any such action.

"(iii) In making a request for additional data beyond that requested by the Administrator, the State shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

"(iv) The applicant may advise the State of comparable data developed or in the process of being developed to satisfy the State's data requirement.

"(C) Any request for data that does not relate to special local concerns as described in subparagraph (B) of this paragraph, and that was not previously submitted to the Administrator in support of a Federal registration, the State shall be reviewable by the Administrator. In reviewing the request, if the Administrator determines that there is a Federal interest, such that the request should be made by the Administrator, the Administrator shall require the applicant to submit the additional data under section 3(c)(2)(B) of this Act. The Administrator may otherwise disapprove the request if the Administrator determines that the request is arbitrary or capricious, or that there is no reasonable basis for making use of the data in connection with a State determination as to registration or approval of the pesticide. Any request for data under this subparagraph shall be submitted to the applicant and at the same time a copy shall be forwarded to the Administrator. If the Administrator has not taken any action within sixty days after receipt of the request for additional data, or fifteen days after receipt by the Administrator of any additional information that may be requested of the

State, approval of the request by the State shall be presumed. Any determination by the Administrator shall be final and not subject to judicial review.

"(3)(A) Except as to applications for which a State, but not a political subdivision of a State, has requested health and safety data that relate to special local concerns as described in paragraph (a)(2)(B) of this subsection, if a State receives an application for a registration, the registration shall be granted pending further review if the State has not affirmatively approved or disapproved the application within—

"(i) sixty days after receipt of the application or such lesser period as may be provided in State law, or

"(ii) if the application for registration involves a restricted use pesticide, or a general use pesticide utilized in the production of a commercial food crop, and the use is a new use of the pesticide or device within a State, or the pesticide contains a new active ingredient, for which the State has not previously granted approval, within one hundred and twenty days or such lesser period as may be provided by State law after receipt of the application accompanied by all data, if any, required by State law and regulations at the time of application, or with appropriate reference to data previously submitted or cited by the applicant. The provi-

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sions of this paragraph shall apply both to cases where the State has made a request for additional data, as well as to cases where the State had not made such a request.

"(B) With respect to applications for which a State has requested health and safety data that relate to special local concerns as described in subsection (a)(2)(B) of this section, a State may prohibit or restrict the sale or use of the pesticide or device within a State for which the application is made pending development, submission, and review of the health and safety data.

"(C) A State may not restrict the sale or use of a pesticide or device within the State for failure of the applicant to submit health and safety data requested by the State to the extent the Administrator has disapproved such request under paragraph (2)(B) or (2)(C) of this subsection.

"(4) The district courts of the United States shall have jurisdiction to review determinations of the Administrator under this subsection and of the States under subsection (a)(2)(B)(ii) of this section that are subject to judicial review and shall have jurisdiction to enforce and to prevent and restrain violations of the provisions of paragraph (3)(A) of this subsection.

"(5) For the purposes of this section, a State shall not be deemed to include any of its political subdivisions or any agency thereof.".

SEC. 2. Section 26 of the Federal Insecticide, Fungicide, and Rodenticide Act is amended by adding a new subsection (d):

"(d) For the purposes of this section, a State shall not be deemed to include any of its political subdivisions or any agency thereof.".

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